CHAPTER 1: INTRODUCTION

1.1 Global pattern of prostate cancer

Prostate cancer is the second most common cancer and the second leading cause of cancer death in man (American Cancer Society, 2011; Cancer Research UK, 2010; Kumar & Anderson, 2002). The incidence of prostate cancer is rising steadily (American Cancer Society, 2011; Nelen, 2007; Sarma & Schottenfeld, 2002) with a global estimated increase of three percent every year (Hankey et al., 1999). There are about one in six men diagnosed during their lifetime (American Cancer Society, 2011; Kumar, Barqawi, & Crawford, 2004) with the median age of 67 years at time of diagnosis (Altekruse et al., 2011).

In year 2000, the percentage of prostate cancer was around 10 where 15.3 percent among total cancer in men were in developed countries and 4.3 percent in the underdeveloped countries (Parkin, Bray, & Devesa, 2001). In 2002, the incidence of prostate cancer in developed countries such as in the United States (US) and New Zealand were greater than 100 per 100,000 populations. Meanwhile, in less developed countries such as Egypt, India and Bangladesh it was around 5 per 100,000 population (American Cancer Society, 2011). In developed countries, prostate cancer is the most often diagnosed cancer and the third leading cause of cancer deaths. Meanwhile, in developing countries, prostate cancer is the sixth most often diagnosed cancer and the sixth leading cause of cancer death (Jemal et al., 2011). In Malaysia, prostate cancer is the sixth most frequent cancer and it accounts for 5.7 per cent of cancer cases in males (Malaysian Urological Association, 2006).

1.2 Psychological Problems in Prostate Cancer Patients

Receiving a diagnosis or treatment for prostate cancer is a significant distressing occasion for a substantial proportion of patients (Meryn, 2007; Sharpley, Bitsika, & Christie, 2008). This situation leads to an increase in anxiety, depression and sadness which consequently affects their quality of life (Bloch et al., 2007). Consultation-liaison psychiatrists and physicians need to be aware of the psychological problems of both prostate cancer and treatment-related side effects (Kunkel, Bakker, Myers, Oyasanmi, & Gomelia, 2000).

Psychological distress screening among prostate cancer patients showed a high degree of distress which required psychiatric referral (32.4 percent anxiety and 15.2 percent depression) (Roth et al., 1998). However, 40 percent of the distressed men refused psychiatric consultation and over half of the men identified were not clinically diagnosed by a psychiatrist. The factors that influence distress include endocrine or metabolic changes associated with cancer or its treatment, cancer prognosis, individual coping style and social support (Roy-Byrne et al., 2008). The primary impact of loss of activities and abilities could be a cause for anxiety and depression among prostate cancer patients (Meryn, 2007).

In longitudinal studies, the psychological adjustment does not worsen over time but patients with early signs of anxiety and depression showed a poorer psychological prognosis (Bloch et al., 2007). In general, one to eight years after diagnosis, the patients do well in psychologic well-being where 90.7 percent reported being happy, 57.9 percent very happy and only 2.7 percent very unhappy (Blank & Bellizzi, 2006). It was reported that patients with localized prostate cancer who were within 18

months of completing treatment had poorer emotional wellbeing. This emotional state was associated with perceived severe consequences of the cancer (Traegera et al., 2009).

On dealing with psychological problems, specific arrangement for counselling and support must be provided for the patients and their family members. The health care providers should offer an opportunity to discuss how patients and family members cope with cancer (Rodin et al., 2009).

1.3 Health Related Quality of Life (HRQOL) in Men with Prostate Cancer

Many studies have been conducted on health related quality of life (HRQOL) among prostate cancer patients (Halbert et al., 2010a; Katz, 2007; Litwin et al., 2007; Potosky et al., 2002; Siston et al., 2003). The HRQOL has grown to be an important factor in clinical care in prostate cancer patients (Quek & Penson, 2006; Talcott & Clark, 1998). Quality of life in prostate cancer patients decreased in short and long terms (Katz, 2007; Penson, Litwin, & Aaronson, 2003b). For both localized and advanced prostate cancer disease, patients in both groups are facing therapeutic alternatives associated with troublesome side effects and functional impairment (Herr, 1997).

In general, socio-economic factors have important impact on HRQOL among prostate cancer patients (Miller & Wei, 2006). Lower income and lack of health insurance are associated with less favourable post-treatment HRQOL (Penson et al., 2001). The higher level of spousal support is associated with better urinary and mental functioning among prostate cancer patients (Eton, Lepore, & Helgeson, 2001).

Lubeck et al., (2001) used The Prostate Strategic Urologic Research Endeavor (CapSURE) dataset and found that African American men had lower HRQOL scores as measured by the SF-36 and The University of Los-Angeles Prostate Cancer Index (UCLA PCI) instruments. Crawford et al., (2001) also found the African American men were more likely to have poorer urinary and sexual function following therapy.

1.4 Treatment for prostate cancer

The factors for prostate cancer treatment depend on how far the cancer has spread, the grade, the Gleason score, the PSA blood test, age and general health of the patient (Bracarda et al., 2005; Cancer Research UK, 2010). The patients have the right to make a decision even though they are facing with difficult treatment decision. Patients who received self-efficacy information played an active role in treatment decision making (Joyce & Lesley, 1997; Rodin et al., 2009).

The treatment for prostate cancer are grouped into two, namely, curative therapy and palliative therapy (William, Cooper, & Donovan, 2003): Curative therapy is for patients with low grade and low-stage incidental lesions that require observation only (Bharnagar & Kaplan, 2005; Bracarda et al., 2005; Heidenreich et al., 2008; William et al., 2003). The alternatives for curative therapy are external beam radiation (EBR) or prostatectomy as the procedure of choice for these patients (William et al., 2003). Choosing among the alternatives are difficult because of long-term side effects that include sexual, urinary and bowel dysfunction (Bharnagar & Kaplan, 2005). Recent advances in surgical technique have led to a low incidence of incontinence (1 – 4 percent) and preservation of potency in up to 70 percent of patients (William et al., 2003). Some recent studies suggest that patients who have chosen treatment (i.e

radical prostatectomy or radiation) have longer disease-free survival compared to patients who have chosen conservative management (i.e. watchful waiting) (Bharnagar & Kaplan, 2005).

Palliative therapy is given for patients with metastatic disease that cannot be cured (William et al., 2003). Androgen deprivation therapy (ADT) in the form of oral estrogen (diethylstilbestrol) or bilateral orchidectomy is effective in 70 to 80 percent of symptomatic patients (American Cancer Society, 2011; William et al., 2003). The choices of therapy depend on the patients' preference. These hormonal treatments are not additive and the use of both treatments simultaneously has no added advantages.

Luteinizing hormone-releasing hormone (LHRH) agonist shows an efficacy comparable to that of estrogen or orchidectomy, with reduced side effects (American Cancer Society, 2011). LHRH is given by an injection every three to four months. Studies have shown that concomitant administration of LHRH anti-androgen (flutamide or bicalutamide) improves survival among prostate cancer patients (American Cancer Society, 2011; Bracarda et al., 2005). Patients who failed to respond to hormonal therapy can be treated by aminogluthethimide or oral corticosteroid (William et al., 2003). Radiation therapy for symptomatic bone lesions can be helpful for prostate cancer with bleeding and obstruction (Bracarda et al., 2005). Occasionally, trans-urethral prostatectomy is required to relieve bladder outlet obstruction (William et al., 2003).

Controversy continues concerning whether to treat asymptomatic patients at time of diagnosis or to wait until symptoms develop (William et al., 2003). There are no definitive studies showing survival advantages with early treatment. Therefore,

treatment is withheld until symptoms occur (William et al., 2003). Active surveillance with delayed intervention is a viable option for carefully selected men with low-risk localized prostate cancer (American Cancer Society, 2011; Baker et al., 2008; Heidenreich et al., 2008).

Pain management is also an important issue in prostate cancer patients with advanced disease. Palliative care and medication may help to relieve the pain (Whelan, 2008). In prostate cancer treatment, physical side effects can lead to emotional, psychological distress and bad spousal relationship. Fears about the disease progression and recurrence, concomitant depression and anxiety have a negative impact on prostate cancer survivors' quality of life (American Cancer Society, 2010).

1.5 Complementary and Alternative Medicine (CAM) in Prostate Cancer Patients

Complementary therapy provides supportive treatment prescribed by the health personnel and alternative therapy used instead of conventional medical treatment (National Center for Complementary and Alternative Medicine, 2007). Complementary differ from alternative therapies in that they do not replace the established therapy (Cassileth, 1999).

Prostate cancer patients also choose to supplement their conventional treatment with one or more forms of CAM. The prevalence of CAM use among prostate cancer patients varies across studies. It is more common in men with higher education, higher income and more advanced disease (Bishop et al., 2011). In Austria, 29.8 percent of prostate cancer patients use at least one form of CAM (Ponholzer, Struhal, & Madersbacher, 2003). Meanwhile, in Ontario Canada, 29.8 percent reported using

CAM for their prostate cancer care with 9.1 percent visiting CAM practitioners (Boon et al., 2003). In the United States, 73 percent among prostate cancer patients taking supplements were mostly among White, more educated and those with healthy lifestyles (Wiygul et al., 2005). A systematic review on prevalence studies by Bishop et al. (2011), found 8 to 90 percent (inter-quartile range of 25 – 43 percent; median of 30 percent) among prostate cancer practicing CAM.

The common reasons for using CAM among prostate cancer patients were concern with physical health status (eg. to treat cancer or side effects) and psychological well-being (e.g. to gain a sense of control or hope) (Bishop et al., 2011; Wiygul et al., 2005). CAM use is more related to other factors such as support group attendance, disease characteristics and belief about CAM (Boon et al., 2003). Many studies on CAM were concentrated on food product supplements like Vitamin E, Vitamin C, fat reducing diet, calcium, saw palmetto and selenium (Boon et al., 2003; Ponholzer et al., 2003; Wiygul et al., 2005). However, not many studies have been carried out on body mind therapy such as relaxation therapy (Complementary Alternative Medicine, 2010).

1.6 Relaxation Therapy

Relaxation therapy is a therapeutic approach that employs various relaxation techniques to treat some psychological problems (Butler, 2010; Hyman, Fieldman, Harris, Levin, & Malloy, 1989). Relaxation therapy has been shown to have a direct physiological effect on the body by interfering with the autonomic nervous system and a psychological effect by improving mood state and reducing tension and depression. During relaxation, it focuses on the mind and relaxes both mind and body.

The aims of relaxation therapy are to calm the mind and allow thoughts to flow in a smooth, level rhythm and induce the relaxation response. It increases an individual's ability to deal with issues outside the therapeutic session. A pilot study by Beard et al. (2011) on relaxation response therapy (RRT) found that RRT improved emotional well-being and eased anxiety. The Reiki therapy that uses a technique called palm healing or hands on healing had a positive effect in reducing anxiousness among prostate cancer patients with radiation therapy (Beard et al., 2011).

1.7 Statement of Problem and research gap

Men with prostate cancer face unique challenges as they deal with their disease, its treatment and their partners (Katz & Katz, 2008). Due to long survival of prostate cancer, they may face with psychological problems like depression, anxiety and stress. In the clinical setting, most urologists concentrated only on the treatment for prostate cancer rather than to treat the patients as a whole. The health professionals need to know other activities that can make life easier for their patients (Gloag, 1985).

Randomized controlled clinical trials (RCT) and qualitative investigations in CAM were interdisciplinary (Adler, 2002). In the primary care setting, there are some relaxation techniques applied to the patients to reduce their anxiety and stress level and a few for depression (Dusek & Benson, 2009). The relaxation technique is inexpensive and easy to learn and has a great potential for wide application in clinical practice (Perez-Stable, 1987). The patients can practice the relaxation therapy at home after having a few sessions with the trained occupational therapist.

There were many studies conducted on different type of relaxation techniques and some of the results showed significant results. However, they did not mention whether their study showed any clinical significance. The result just showing only effect size was not enough to conclude that the relaxation therapy was effective in improving any psychological problems and quality of life.

The lack of research using applied progressive muscle relaxation training (APMRT) to alleviate depression, anxiety and stress and increase the HRQOL level motivated the researcher to conduct this study using a quasi-experimental method. Many studies have been conducted using different types of relaxation therapy to investigate their impact on psychological problems and quality of life. There have shown significant difference. However, not many studies have mentioned whether the impact showed any clinical significance.

This study will provide an understanding of the impact of APMRT on psychological problems and HRQOL. This research hopes to provide valuable information for healthcare professionals with the aim of improving patient's psychological problems and QOL.

1.8 Conceptual Framework

This study is aimed to assess the impact of applied progressive muscle relaxation training (APMRT) therapy on the levels of depression, anxiety, stress and quality of life. The domains for the HRQOL that are assessed include physical component summary (PCS), mental component summary (MCS) and overall quality of life (QOL). The prostate cancer patients' socio-demographic characteristics, past medical

and surgical illnesses, current urinary symptoms and current cancer status are also assessed.

The conceptual framework of this study is shown in Figure 1.1

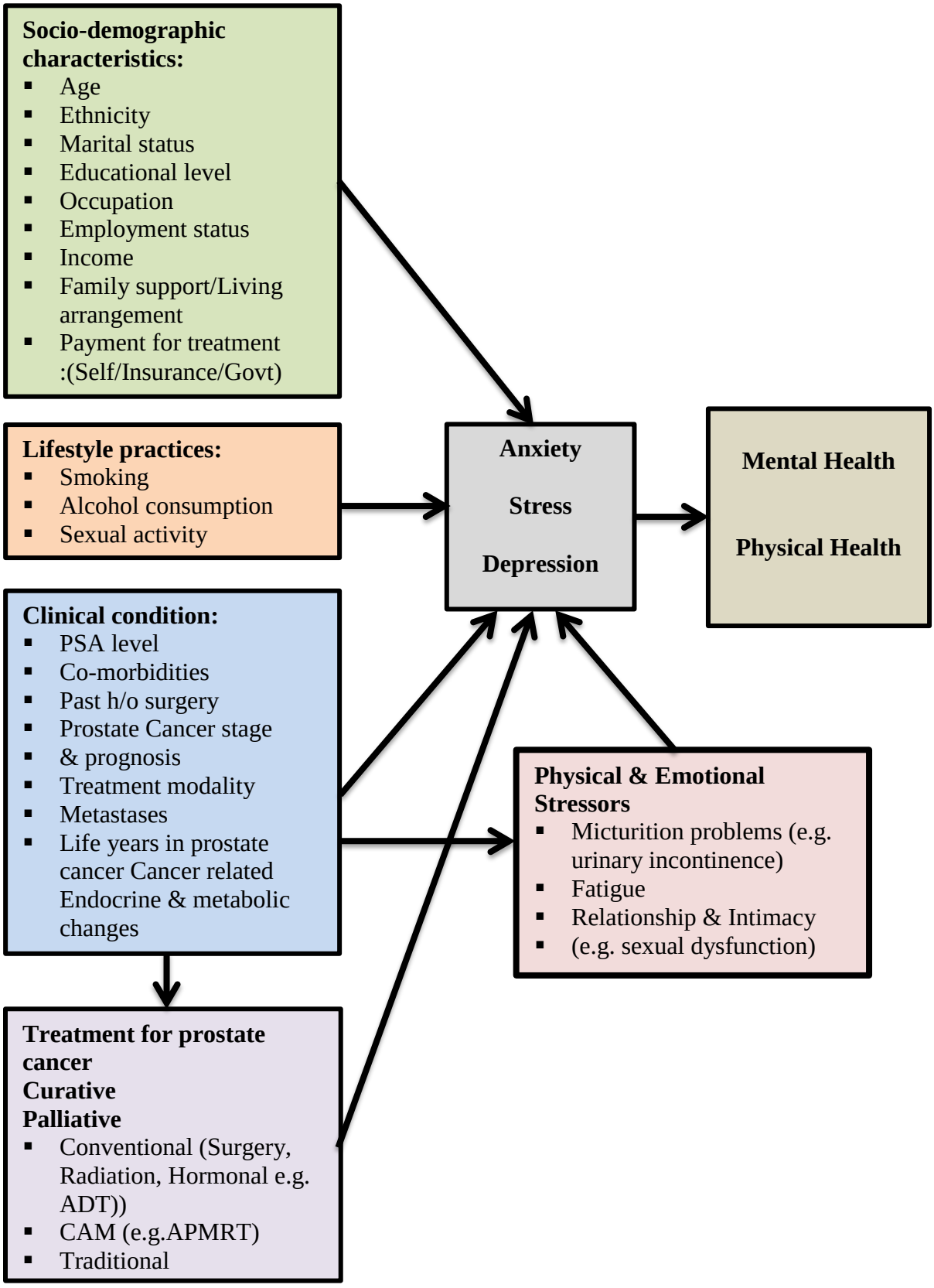


Figure 1.1: Conceptual Framework for Depression, Anxiety, Stress and Quality of life among prostate cancer patients

1.9 The Hypothesis

The study is designed to test the hypothesis that the APMRT can improve the general HRQOL and to reduce the levels of depression, anxiety and stress among prostate cancer patients. Based on this framework, the following hypotheses are derived:

i. There is a significant difference in the depression score between intervention and comparison groups after applied progressive muscle relaxation training.
ii. There is a significant difference in the anxiety score between intervention and comparison groups after applied progressive muscle relaxation training
iii. There is a significant difference in the stress score between intervention and comparison groups after applied progressive muscle relaxation training
iv. There are significant differences in the physical component summary (PCS), mental component summary (MCS) and total quality of life between intervention and comparison groups after applied progressive muscle relaxation training.

1.10 Objectives of the Study

1.10.1 General Objective:

To evaluate the impact of applied progressive muscle relaxation training (APMRT) in health related quality of life, depression, anxiety and stress levels among prostate cancer patients.

1.10.2 The specific objectives are:

i. to compare the baseline socio-demographic characteristics between intervention and comparison group.

ii. to compare the baseline scores of depression, anxiety and stress, eight domains, self-reported healt htransition and two component summaries of health related quality of life (HRQOL) between intervention and comparison group.

iii. to compare the baseline classification of depression, anxiety and stress between intervention and comparison group.

iv. to compare the impact of intervention (APMRT and Conventional) on the general health related quality of life (HRQOL) between intervention and comparison group.

v. to compare the impact of intervention (APMRT and Conventional) on the levels of depression, anxiety and stress between intervention and comparison group.

vi. to compare the classification of depression, anxiety, stress and self-reported transition at baseline and at 6-month between intervention and comparsion group.

CHAPTER 2: LITERATURE REVIEW

2.0 Introduction

This chapter covers several parts of literature review, that relate to the contents of this dissertation. It includes the epidemiology of prostate cancer; psychological problems pertaining to depression, anxiety and stress, the general health related quality of life (HRQOL); and progressive muscle relaxation (PMR) therapy.

The systematic review on progressive muscle relaxation is presented in Table 2.7. The following paragraphs describe the search strategy. The identification of the systematic review was identified by searching seven scientific bibliographic databases from their inceptions including Cochrane Library (Cochrane Central Register of Controlled Trials), PubMed, OVID, MEDLINE, PsycINFO, CINAHL and Science Direct with full text. Internet search engines such as Google Search and Yahoo Search were also used to locate the grey literature. Some hand searches were also carried out in books, theses and non-indexed journals.

The search term combination captured citations with relevant study populations using relevant medical subheading terms and text word. Search terms included: [“prostate cancer” OR “prostate carcinoma”] AND [“progressive muscle relaxation” OR “progressive muscle relaxation training” OR “relaxation training”] AND [depression OR anxiety OR stress OR “health related quality of life” OR “quality of life”]. Titles and abstracts of the citations were scanned to identify potential articles for the review. Potential eligible papers were retrieved in hard copy for more detailed review.

2.1 Prostate

2.1.1 Anatomy of Prostate Gland

The prostate gland is an organ shaped like a "walnut". It weighs approximately 20 gram. The gland wraps around the urethra and is located in front of the rectum at the base of the male bladder (Kumar, Abbas, Fausto, Robbins, & Ramzi, 2005; Mackie, 2010; Pahuja et al., 2006). It is the largest accessory gland of the male reproductive system (Pahuja et al., 2006). It is a fibro-muscular glandular organ that surrounds the prostate urethra (Pahuja et al., 2006; Snell, 1995). Two ejaculatory ducts pierce the posterior surface of the prostate and open into the prostatic part of the urethra, close to the margin of the prostatic utricle (Snell, 1995).

The prostate gland is incompletely divided into five lobes (Pahuja et al., 2006; Snell, 1995): (i) the anterior lobe lies in front of the urethra and it is devoid of glandular tissue; (ii) the median or middle lobe is the wedge of gland situated between the urethra and the ejaculatory ducts; (iii) the posterior lobe is situated behind the urethra and below the ejaculatory duct; (iv) the right and left lateral lobes lies on either side of the urethra and are separated from each other by a shallow vertical groove on the posterior surface of the prostate. In the adult, the prostatic parenchyma is divided into four biologically and anatomically distinct zones or regions (Kumar et al., 2005; Pahuja et al., 2006): (i) peripheral; (ii) central; (iii) transitional zones; and (iv) the region of the fibro-muscular stroma. The occurrence of proliferative lesions is different in each region where most hyperplasia arises in the transitional zones. Most carcinoma originates in the peripheral zone. The prostate gland makes some of the fluid that protects and nourishes sperm cells in semen thus making the semen more liquid. It

produces fluid that joins the semen, the viscous substances that transports sperms through the man's reproductive system and out of the body during ejaculation (Mackie, 2010; Rothfeld & Romaine, 2005).

Histologically, the prostate gland is a compound tubulo-alveolar organ, which in one plane of section presents as a small to fairly large glandular spaces lined by epithelium. Characteristically, the gland is lined by two layers of cells which are the basal layer of low cuboidal epithelium covered by a layer of columnar secretory cells (Kumar et al., 2005). There are three pathologic processes that can affect the prostate gland. They are inflammation, benign nodular enlargement and tumour (Kumar et al., 2005; Mackie, 2010). Figure 2.1 shows the male reproductive system and the location of the prostate gland.

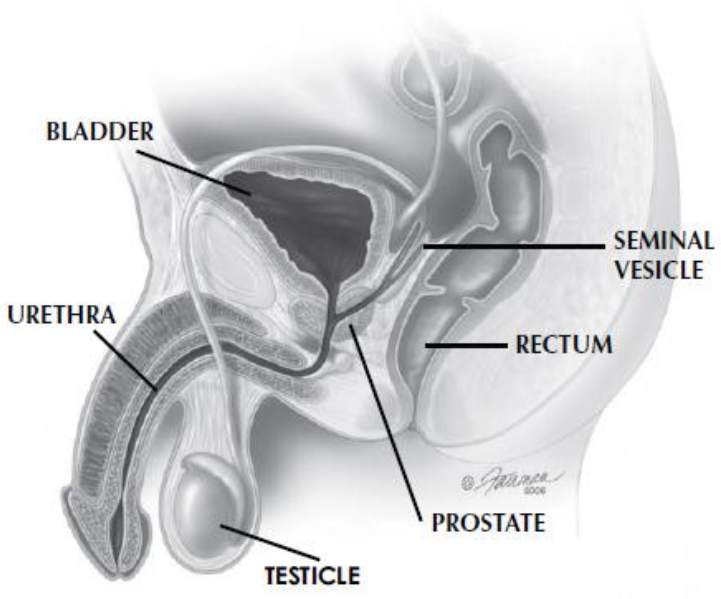


Figure 2.1: Male reproductive tract and the prostate gland
(American Urological Association, 2008)

2.1.2 Epidemiology of Prostate Cancer

2.1.2.1 Global

In the United States (US), it was estimated that there were 240,890 new cases of prostate cancer in year 2010 (American Cancer Society, 2011) and the incidence was comparable in US Black; who exhibited an average of 50 percent higher incidence than Whites (Sarma & Schottenfeld, 2002). In the United Kingdom (UK), prostate cancer was also the highest cancer in men, excluding non-melanoma skin cancer (Cancer Research UK, 2010; Mackie, 2010)**.** Over the last 30 years prostate cancer rates in the UK have almost tripled, although much of the increase was due to an increase in detection through widespread use of prostatic specific antigen (PSA) test (Cancer Research UK, 2011)**.** In 2007, 36,100 men were diagnosed with prostate cancer (Cancer Research UK, 2010) and in 2008, 338,000 men were diagnosed with prostate cancer in European countries (EU-27) (Cancer Research UK, 2011). In the Netherland, the age-adjusted incidence increased from 37 per 100,000 populations in 1975 to 55 per 100,000 populations in 1989. However, after introduction of PSA screening, the incidence further increased to 80 per 100,000 population in 1995 (Post, Kil, Crommelin, Schapers, & Coebergh, 1998)**.**

In Asia, the cases of prostate cancer is lower compared to Western countries (Kumar et al., 2005; Sim & Cheng, 2005). The incidence of prostate cancer has risen by 5 – 118 percent in the Asian countries (Sim & Cheng, 2005). The incidence of prostate cancer in Japan rose by 102 percent while the incidence among Singaporean Chinese increased 118 percent from 6.6 to 14.4 per 100,000 person-years (Sim & Cheng, 2005). In 1990, the age-adjusted prostate cancer incidence rate was 8.5 per 100,000 populations and

increased approximately two-fold to 16.1 per 100,000 populations in 1995. The increasing incidence of prostate cancer in Japan was likely due to "westernization' of their diet (Crawford et al., 2001).

Several hypotheses have been proposed why the incidence of prostate cancer has increased. These are: (i) the frequent prostatic specific antigen (PSA) screening during the past 15 years enabled early detection and diagnosis and thus offering the chance for cure (Hankey et al., 1999); (ii) the aging population in developed countries resulting in a steady increase of elderly people and the longer life expectation (Ries, Melbert, & Krapcho, 2008); and (iii) exposure to environmental carcinogens and increasing use of novel treatment modalities (Haas & Sakr, 1997).

2.1.2.2 Malaysia

The National Cancer Registry, Ministry of Health (MOH), Malaysia produced a National Cancer Registry (NCR) Report using the CanReg system. The first report for all cancers was in year 2002 (Gerard Lim, Yahaya, & Lim, 2003). Table 2.1 summarizes the prostate cancer registry in year 2002 (Gerard Lim et al., 2003), 2003 (Gerard Lim & Yahya, 2004), 2003 to 2005 (Gerard Lim, Rampal, & Yahya, 2008) and 2007 (Omar & Ibrahim-Tamin, 2011).

Table 2.1: Prostate Cancer Registry, Malaysia

Year	2002*	2003*	2003-2005*	2007#
Rank	6th	6th	4th	4th
Number of cases	671	602	2150	502
Crude rate (CR) (per 100,000 population)	6.8	6.2	7.3	3.9
Adjusted Standardization Rate (ASR) (per 100,000 population)	11.6	10.3	12.0	6.2

* Peninsular Malaysia; # Malaysia
Sources: National Cancer Registry, Malaysia

Prostate cancer in Malaysia is expected to move up in position with an increasingly ageing population in Malaysia (Gerard Lim, 2003). A study in *Hospital Universiti Sains Malaysia* (HUSM) found that prostate cancer is on the rise compared to other cancers in the male population (Othman, Mohd Nor, & Biswal, 2008).

2.1.3 Mortality

Globally, approximately 13 percent of all cancer death was due to prostate cancer (Albertsen, Fryback, Storer, Kolon, & Fine, 1995). In year 2010, it was estimated that 32,050 men were expected to die from prostate cancer in the United States (US) (American Cancer Society, 2011).

In the US, prostate cancer was the second highest cause of death after lung cancer (American Cancer Society, 2011). Between year 1976 to 1994, the mortality increased by 20 percent and from 2003 - 2007 and the median age at death was 80 years of age. The age adjusted death rate was 24.7 per 100,000 men per year (Altekruse et al., 2011).

In 2002 – 2006, the mortality rate for White men was 23.6 per 100,000 and for African American was 56.3 per 100,000 (American Cancer Society, 2011). The death rates also varied between different races. Data from 1992 - 1999 showed that African - Americans have a rate five times higher compared to Asians, three times higher compared to Hispanics, (Clegg, Li, Hankey, Chu, & Edwards, 2002) and twice higher compared to Whites (Sarma & Schottenfeld, 2002).

In the United Kingdom (UK), prostate cancer was the second most common cause of cancer death among men. In 2008, there were 10,170 men in the UK and more than 70,000 men in Europe who died from prostate cancer (Cancer Research UK, 2010). In the Netherlands, the age-adjusted mortality declined in the early 1970s but increased slightly from 22 per 100,000 populations in 1973 to 26 per 100,000 populations in 1980. The increase was apparent for all age groups. The age-adjusted mortality increased again in 1980s mainly due to increase in men aged 55 – 64 years in the population. It was 12 per 100,000 in 1980 and increased to 25 per 100,000 population in 1989 (Post et al., 1998).

The mortality rate in Asian countries showed a similar rising trend with age-adjusted mortality rates per 100,000 person-years, ranging from 50 percent in Thailand to 260 percent in Korea (Sim & Cheng, 2005). The large difference could be due to genetic polymorphism in the androgen receptor and androgen metabolism pathway enzymes as well as dietary or environmental factors (Sim & Cheng, 2005).

After introduction of PSA screening, there was a small increase in age-adjusted mortality from 26 per 100,000 populations in 1990 to 32 per 100,000 populations in 1995 (Post et al., 1998). The mortality rates declined in developed countries due to

earlier detection and improved treatment (Parkin et al., 2001). With an increase in detection at the earlier stage of the disease in younger men, and earlier treatment, a significant fall in the mortality rates were also observed (Kumar & Anderson, 2002).

2.1.4. Survival

Prostate cancer survival showed a significant variation when comparing developing and developed countries. In developed countries the global 5-year survival was 70 – 90 percent and as low as 40 percent in developing countries (Albertsen et al., 1995). The survival rates for prostate cancer improved during the last 30 years. Over the past 25 years, the overall relative 5-year survival for prostate cancer increased from 69 percent to 99.6 percent. The 10-year survival is estimated to be around 95 percent and 15-year survival is around 82 percent (American Cancer Society, 2011).

In the 1970s, only two in 10 men diagnosed with prostate cancer survived for at least 10 years. Currently, more than three-quarters of men diagnosed with prostate cancer survive more than five years (Cancer Research UK, 2010). Data from Surveillance Epidemiology and End Results (SEER) Cancer Statistics Review 1975 - 2007 showed the overall five-year relative survival rate among Americans was 99.1 percent with 99.6 percent for White men and 95.9 percent for Black men (Altekruse et al., 2011). The SEER data from 1973 to 1990 also found that married patients had a significantly longer median survival when compared to non-married patients (Krongrad, Lai, Burke, Goodkin, & Lai, 1996). Due to long term side effects, the integration of survival outcome with quality of life is very important in the treatment of prostate cancer patients (Bharnagar & Kaplan, 2005).

With good nutrition and medical care, more Asians have longer life expectancy and more men live longer after being diagnosed with prostate cancer (Sim & Cheng, 2005). In most cases, prostate cancer has a long preclinical phase between onset and the appearance of clinical symptoms. Therefore, the measure of survival time for prostate cancer is easily confounded by lead time bias (Bharnagar & Kaplan, 2005; Parker, Muston, Melia, Moss, & Dearnaley, 2006). Lead time bias is the difference in time between screen detection and clinical detection in the absence of screening (Last, 1998). It was estimated that the lead time was five to 12 years but it varies with a man's age at time of screening (Draisma, 2003; Pashayan, Powles, Brown, & Duffy, 2006).

2.1.5 Pathogenesis of Prostate Cancer

Prostate cancer is a slow growing disease and little is known about the aetiology (Kumar et al., 2005; Mackie, 2010). It often has no symptoms in the early stages (Mackie, 2010). The pathogenesis of prostate cancer likely involves the interplay between environmental and genetic factors (Boyle, Severi, & Giles, 2003). In nodular hyperplasia of the prostate, androgens are believed to play a role in the pathogenesis of prostate cancer. It is supported by the evidence that inhibition of this tumour can be achieved by orchidectomy (Kumar et al., 2005). It can be plausibly suggested that several factors are involved in the neoplastic transformation of prostate cancer in prostate cancer pathogenesis where aging increases intracellular oxidative stress and oxidative damage (Minelli, Bellezza, Conte, & Culig, 2009).

Prostate cancer is a malignant tumour. Initially it affects the small glands inside the prostate, and progress slowly and remains confined in it. Subsequently, the cancer

spreads beyond the prostate capsule, invading the nearby tissues and organs. In the later stages the cancer spreads and metastasize to the pelvic lymph nodes and the bones (Johansson et al., 2004). Some researchers believe that prostate cancer begins as a pre-cancerous condition called prostatic intraepithelial neoplasia (PIN)(American Cancer Society, 2011). PIN appears in the prostate of some men as early as their 20 years old and almost half men have PIN by the age of 50 years old. Then the cell grows and changes into low-grade (normal) and high-grade (abnormal) differentiation before the cells multiply and become a tumour.

2.1.6 Types of Prostate Cancer

More than 95 percent of prostate cancers are adenocarcinoma (a form of cancer which originates from the epithelial cells in the prostate gland) (Bracarda et al., 2005; Gerard Lim et al., 2008; Kumar et al., 2005; Kumar & Anderson, 2002; Mackie & Rai, 2008). Other types of cancer can start in the prostate gland, including squamous cell carcinoma, signet-ring carcinoma and transitional cell carcinomas (Bracarda et al., 2005; Gerard Lim et al., 2008; Kumar et al., 2005; Kumar & Anderson, 2002).

Approximately, 70 percent of prostate adenocarcinoma occur in the peripheral zone, 20 percent occur in the transitional zone and 10 percent occur in the central zone (Moul, Pienta, Hollenbeck, & Ray, 2005). The molecular pathogenesis of prostate cancer involves many factors such as alterations in signal transduction pathways, angiogenesis, and cell cycle control (Gimba & Barcinski, 2003).

2.1.7 Risk factors of Prostate Cancer

The causes of prostate cancer remain poorly understand. However, some epidemiological studies suggest a correlation between prostate cancers and a number of risk factors. Risk factor is anything that affects chances of getting a disease such as cancer. It is an aspect of personal behavior or lifestyle, an environmental exposure or inborn or inherited characteristic, which on the basis of epidemiologic evidence is known to be associated with health-related condition(s) considered important to prevent (Last, 1998).

Artificial neural networks (ANN) can be applied to predict prostate cancer. It can complement with traditional statistical techniques to predict the development of prostate cancer. However, it has a tendency to over fitting the data used and lacks transparency relative to other statistical methods (Gamito, Crawford, & Errojon, 2003). By identification of the potentially modifiable risk factors, proper public health intervention can be implemented (Subair, Shah, & Md-Zainuddin, 2009). Some of the following have been identified to be risk factors for prostate cancer (Kumar et al., 2005; Mackie, 2010).

2.1.7.1 Age

Age is the strongest risk factor for prostate cancer (American Cancer Society, 2011; Bardan, Bucuras, Dema, & Botoca, 2007; Cancer Research UK, 2011; Hsing & Chokkalingam, 2006; Mackie, 2010; Reiter & de Kernion, 2002). Prostate cancer is very rare before the age of 40, but the risk rises rapidly after age 50 (Cancer Research UK, 2010; Haas & Sakr, 1997; Kumar et al., 2004; Kumar et al., 2005; Malaysian

Urological Association, 2006). More than 80 percent of diagnosed prostate cancer patients are more than 65 years old or older (American Cancer Society, 2011; Haas & Sakr, 1997; Kumar et al., 2005; Kumar & Anderson, 2002).

In 1998, Malaysia's population was 21.4 million, where four percent were aged 65 years and above. The incidence of cancer is expected to rise with an increase in aging population (Gerard Lim, 2002) and the age specific prostate cancer incidences in Malaysia will followed the same trend (Gerard Lim et al., 2008; Gerard Lim et al., 2003; Gerard Lim & Yahya, 2004; Omar & Ibrahim-Tamin, 2011). The age specific cancer incidence in year 2002, 2003, 2003 - 2005 (Peninsular Malaysia) and 2007 (Malaysia) are shown in Table 2.2.

Table 2.2: The age specific prostate cancer incidence (per 100,000 populations)

Age groups	Year			
	2002*	**2003***	**2003 – 2005***	**2007****
0 – 9	0	0.2	0.1	0
10 – 19	0	0.2	0	0
20 – 29	0.2	0.2	0.1	0
30 – 39	0.1	0.5	0.1	0
40 – 49	0.7	0.9	0.5	0.6
50 – 59	10.5	9.4	9.7	5.5
60 – 69	58.1	52.2	60.4	33.7
≥ 70	161.8	137.9	167.7	85.9

* Peninsular Malaysia, ** Malaysia
Source: National Cancer Registry, Malaysia

2.1.7.2 Race

The variation in distribution of prostate cancer cases internationally may reflect genetic factor that vary in populations originating in different parts of the world (American Cancer Society, 2011; Bardan et al., 2007; Hsing & Chokkalingam, 2006). Migratory studies have documented that Japanese men who migrated to the United States (US) had increased incidence of prostate cancer due to a change in dietary pattern and the risk is higher among those who migrated at a younger age (Crawford et al., 2001; Shimizu et al., 1991).

In the United State (US), the African American men are at higher risk for prostate cancer compared to White men (American Cancer Society, 2011; Gallagher & Fleshner, 1998; Haas & Sakr, 1997; Kumar et al., 2004; Kumar & Anderson, 2002; Mackie, 2010). In 2002 - 2006, it was estimated that the age-adjusted incidence rate for White men was 146.3 per 100,000 population and for African American was 231.9 per 100,000 population (American Cancer Society, 2011). They are more likely to develop prostate cancer at an earlier age and to have aggressive tumours that grow quickly.

West African and Black men from the Caribbean were at higher risk compared to White men (Cancer Research UK, 2010). However, Jamaican men in Kingston have a much higher incidence of prostate cancer compared to Black Americans (Glover et al., 1998). Hispanics have lower risk compared to Whites with 172.9 per 100,000 population (Clegg et al., 2002). A study by Bunker et al., (2002) found that men of African descent share genetic and/or lifestyle factors that contribute to their elevated risk for prostate cancer.

Men born in Asia have a lower risk of prostate cancer compared to Asian men born in the UK (Cancer Research UK, 2010; Kumar et al., 2004) with 107.1 per 100,000 population (Clegg et al., 2002). In Malaysia, Chinese men have the highest incidence compared to Indian and Malay men (Gerard Lim et al., 2008; Gerard Lim et al., 2003; Omar & Ibrahim-Tamin, 2011). However, in second report of the National Cancer Registry Incidence in Malaysia year 2003, Indian men was ranked the highest (Gerard Lim & Yahya, 2004).

Table 2.3 shows the prostate cancer incidence and age standardized incidence rate by ethnic group in Malaysia.

Table 2.3: The Prostate Cancer incidence (per 100,000 populations) by Ethnicity

Year	Ethnicity	No. (%)	CR (per 100,000 populations)	ASR (per 100,000 populations)
2002*	Malay	273 (42.1)	4.7	9.2
	Chinese	325 (50.1)	12.5	15.7
	Indian	51 (7.9)	5.9	11.5
2003*	Malay	214 (37.9)	3.6	7.0
	Chinese	284 (50.3)	10.8	13.0
	Indian	67 (11.9)	7.6	14.0
2003-2005*	Malay	728 (33.9)	4.0	7.7
	Chinese	1083 (50.4)	13.6	15.8
	Indian	209 (9.7)	7.8	14.8
2007**	Malay	176 (35.2)	2.5	4.9
	Chinese	264 (52.6)	8.2	8.7
	Indian	31 (6.2)	3.3	5.8

* Peninsular Malaysia, ** Malaysia
CR: Crude rate; ASR: Age Standardized Rate
Source: National Cancer Registry, Malaysia.

The prevalence of prostate cancer at different ages is similar across various ethnic groups, though the incidence of prostate cancer varies greatly among different ethnic groups (Haas, Delongchamps, Brawley, Wang, & Roza, 2008).

2.1.7.3 Family History

It have been documented that there was an increase in the prostate cancer incidence among men who have a family history of prostate cancer (American Cancer Society, 2011; Bardan et al., 2007; Bratt, 2002; Hsing & Chokkalingam, 2006; Kumar et al.,

2004; Mackie, 2010). It could be attributed to a specific gene which may be associated with this cancer (American Cancer Society, 2011). One or more first-degree relatives (father, brother or son) diagnosed with prostate cancer have an increased risk, especially if the relative was diagnosed before the age of 60 (American Cancer Society, 2011; Cancer Research UK, 2010, 2011; Gallagher & Fleshner, 1998; Gallus et al., 2007; Haas & Sakr, 1997; Lightfoot et al., 2004).

When a man has prostate cancer, the relative risk for his first-degree relatives increases by two to three times. Meanwhile, when two close relatives have the disease, the relative risk rises to six-fold (Kumar & Anderson, 2002). A case control study in Malaysia found the risk of prostate cancer among men who had a first degree relative was 3.8 (Subair et al., 2009). Currently, men with a family history of prostate cancer are provided advice in terms of preventive action.

2.1.7.4 Nutrition and Dietary Supplements

No study has shown conclusively that diet can directly influence the development of prostate cancer (American Cancer Society, 2011; Cancer Research UK, 2010). Some epidemiologic studies implicated that high dietary fats were a causal factor for prostate cancer (Gallagher & Fleshner, 1998; Haas & Sakr, 1997; Kolonel, Nomura, & Cooney, 1999). High consumption of coffee and bread (Gallus et al., 2007) and alcohol (Kolonel et al., 1999) were related to prostate cancer. Food high in arachidonic acid and linolenic acid (such as meats) increase testosterone production and appear to fuel the growth of prostate cancer cells (Rothfeld & Romaine, 2005).

Low fat diet, vegetables (Gallagher & Fleshner, 1998; Gallus et al., 2007; Haas & Sakr, 1997), fruits (Gallagher & Fleshner, 1998; Gallus et al., 2007; Haas & Sakr, 1997; Subair et al., 2009) and legumes may help to reduce the risk of prostate cancer (Gallagher & Fleshner, 1998; Gallus et al., 2007; Haas & Sakr, 1997). The cruciferous vegetables e.g. broccoli, Brussels sprouts, cabbage, cauliflower, horseradish, kale, kohlrabi and rutabaga which contain the anti-toxidants sulforaphare and isothiocyanate are prostate cancer-fighting factors that can reduce the risk of prostate cancer (Rothfeld & Romaine, 2005). Soya-based foods and soy protein contain oflavones which have protective effects on prostate gland. The Oflavones are also ables to kill prostate cancer cells before they can grow into tumours (Rothfeld & Romaine, 2005).

Selenium is a trace element that is incorporated into protein to seleno-protein which is an important antioxidant enzyme. It has an anti-carcinogenic effect that is thought to be induced by the production of methylselenol that affects gene expression and modifies cell cycling and has immune function that can reduce the risk of prostate cancer (Boyle et al., 2003; Fleshner & Klotz, 1999; Lippman et al., 2005; Salama, Sakr, & Reinhart, 2007). Dietary supplements of Vitamin E (Boyle et al., 2003; Fleshner & Klotz, 1999; Gallagher & Fleshner, 1998; Gallus et al., 2007; Haas & Sakr, 1997), zinc (Boyle et al., 2003) and lycopene (Boyle et al., 2003; Lippman et al., 2005; Mackie, 2010) reduce risk of prostate cancer. In vitro studies have demonstrated that omega-6 fatty acids stimulate the growth of the tumors cells, while omega-3 fatty acids inhibit them (Kolonel et al., 1999).

2.1.7.5 Hormone

Maturation and normal growth of the prostate gland are influenced by androgen (American Cancer Society, 2011; Sim & Cheng, 2005). Testosterone diffuses into prostate cells and is irreversibly converted to dihydrotestosterone (DHT) by 5-reductase. Both testosterone and DHT bind to the androgen receptors which then initiate DNA transcriptional activity and prostate cell division (Sim & Cheng, 2005). High levels of androgen (a male sex hormone) may speed up or cause the development of prostate cancer (Bardan et al., 2007; Haas & Sakr, 1997; Hsing & Chokkalingam, 2006; Reiter & de Kernion, 2002). However, the study which correlated hormones and prostate cancer has been complicated by measurement issues related to normal changes in hormone level as men get older (American Cancer Society, 2011).

2.1.7.6 Environmental Factors

It has been suggested that environmental factors are involved in the progression of clinically insignificant cancer to significant cancer (Wang, 2009). Excessive exposure to gamma radiation, high concentrations of cadmium or aromatic hydrocarbonates increased the risk of prostate cancer (Abd Elghany, Schumacher, Slattery, West, & Lee, 1994; Kumar & Anderson, 2002; Mackie, 2010). Employment in a nuclear power industry has been suggested as factors that may promote prostate cancer (Kumar & Anderson, 2002). A case control study by Subair et al., (2009), found that frequent exposure to pesticides will also increase the risk of prostate cancer. However, high exposure to sun can reduced the risk of advanced prostate cancer (American Cancer Society, 2011; John, Schwartz, Koo, Berg, & Ingles, 2005).

2.1.7.7 Sexual Activity

There are many possible factors related to sexual activity for prostate cancer. Introduction to sexual activity earlier in life (Dimitropoulou et al., 2008; Honda et al., 1988; Kumar & Anderson, 2002), having multiple sex partners (Honda et al., 1988; Kumar & Anderson, 2002), sexually transmitted disease (STD) (Kumar & Anderson, 2002), history of vasectomy (Kumar & Anderson, 2002) and frequent masturbation in the 20s to 30s have been suggested as possible risk factors for prostate cancer. Meanwhile, frequent sexual activity (Dimitropoulou et al., 2008; Subair et al., 2009) and masturbation in the 50s (Dimitropoulou et al., 2008) have been found to be protective against the prostate cancer. However, from all the above none have been substantiated.

There is no association between marital status and risk of prostate cancer (Subair et al., 2009). However, there was a significant higher number of marriages among prostatic cancer patients compared to controls. The relative risk of prostatic cancer was 3.2 (95%CI: 1.2 – 8.9) for two or more marriages compared to never married men for the risk of prostate cancer (Vecchia et al., 1993).

2.1.7.8 Genetic Factors

A large number of studies have been conducted for the potential genetic factors associated with prostate cancer. Men with BRCA-2 mutation are at higher risk for prostate cancer that is more aggressive and develops at the younger age. Consistent evidence from genetic studies have identified that locations on chromosome 8 (in a region called 8q24) was associated with an increased risk of developing prostate cancer

and with more aggressive prostate cancer (American Cancer Society, 2011; Bardan et al., 2007; Reiter & de Kernion, 2002). The most common regions of gains in hormone-refractory prostate cancer concentrated on two chromosomal regions, 8q and Xq (Visakorpi, 2004). It was estimated that 42 percent of prostate cancer risk was accounted by genetic influences, including individual and combined effect, highly penetrating genes, and genes acting in concert with each other (Hsing & Chokkalingam, 2006).

Prostate cancer risk associated with genetic status resulted from two mechanisms (Cussenot, 2004): (i) genetic predisposition associated with very high risk can explain hereditary prostate cancer in the case of an inherited mutation involving predisposing loci; and (ii) genetic mechanism can result from genetic susceptibility, via individual or ethnic polymorphisms that involve mostly androgen metabolism.

2.1.7.9 Physical Activity and Obesity

Obesity is associated with more sedentary life-style and decreased frequency of exercise. Regular exercise correlates with a slower growth of prostate cancer cells, through the effects of improved immune system function (Hsing & Chokkalingam, 2006; Rothfeld & Romaine, 2005). However, a case control study in Taiwan found that those who engage with more physical activity had a higher risk for prostate cancer compared to those with compared to those with less physical activity (adjusted odds ratio: 2.16) (Pu, 2000).

Obesity increases the risk of prostate cancer (Gallagher & Fleshner, 1998; Hsing & Chokkalingam, 2006). An obese man had 2.2 higher risk for prostate cancer compared

to man with normal body mass index (BMI) (Macinnis, English, Gertig, Hopper, & Giles, 2003).

2.1.8 Screening for Prostate Cancer

Screening is one of the primary prevention tools for prostate cancer (Harris & Lohr, 2008). It is a presumptive identification of unrecognized disease or defect by the application of tests, examination or other procedures which can be applied rapidly (Last, 1998). The purpose of a screening test is to identify the presence of a specific disease in individuals who do not demonstrate any symptoms. It allows for early detection that can save life if the disease is detected by screening. Early detection through screening is the only possibility to reduce cancer-related mortality and improve therapy (Brawer, 1995; Ilic, O'Connor, Green, & Wilt, 2006).

The goal of early detection in prostate cancer is to identify men who are asymptomatic and to detect the disease at the early stages since the treatment will be most likely to be effective (American Urological Association, 2000; Harris & Lohr, 2008; Schmid, Riesen, & Prikler, 2004). Prostate cancer screening cannot be justified in a low-risk population, however the balance of benefit and harm are more favourable after risk stratification (Frankel, Smith, Donovan, & Neal, 2003).

The primary endpoint of screening in prostate cancer is to reduce the prostate cancer specific mortality and to improve the QOL, expressed by quality of life adjusted gain in life years (QALYs) (Schmid et al., 2004). The American Urological Association added two widely used tests in prostate cancer screening namely Digital Rectal Examination

(DRE) and Prostate-Specific Antigen (PSA) (American Urological Association, 2000; Smith, Cokkinides, & Eyre, 2003).

2.1.8.1 Digital Rectal Examination (DRE)

Digital rectal examination (DRE) is a quick manual examination to check for prostate gland enlargement. This is the first step in diagnosing prostate cancer. By using a gloved finger to examine the rectum, the investigator may be able to feel a hard lump or growth in the prostate gland. The examination takes less than 5 minutes to conduct (Figure 2.2). Asymmetrical gland, the presence of nodules, hard consistency, obliteration of medial sulcus and fixity are the characteristic signs for the suspicion of prostate cancer on DRE (Kumar & Anderson, 2002).

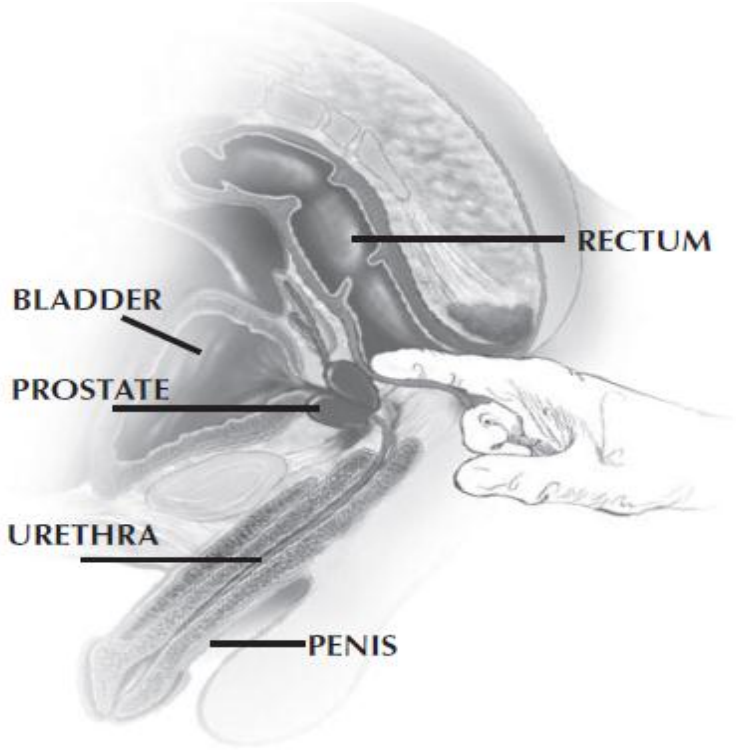


Figure 2.2: Digital Rectal Examination (American Urological Association, 2008)

2.1.8.2 Prostatic Specific Antigen (PSA)

Beginning in 1988, a marked increase in detection of prostate cancer occurred due to the development of a test for prostate-specific antigen (PSA) (Chodak, 2006; Mackie, 2010). This test has been approved by the Food and Drug Administration (FDA) in 1986 as a method to monitor prostate cancer progression (Gagne, 2009). PSA is not a diagnostic test for prostate cancer. The only way to confirm prostate cancer is through biopsy. Monitoring PSA after prostate cancer treatment is essential (Katz & Katz, 2008)

PSA is a neutral protease consisting of a 34-kilodalton single-chain glycoprotein of 240 amino acid residues with a carbohydrate side chain (Lai et al., 2003). It is involved in the liquefaction of semen which is necessary for optimizing chances of ovum fertilization. The level of serum PSA is high in prostate cancer but low in healthy semen (Mackie & Rai, 2008). The PSA test needs blood taking and the adverse effects are mild such as dizziness, bruising and hematoma (Mackie, 2010). Prior to the test, men have an opportunity to learn about the benefits and limitations of testing for early prostate cancer detection and treatment. Then, they can make a decision with a clinician's assistance (Smith et al., 2003).

Although screening using PSA test may help in detecting prostate cancer, screening for prostate cancer using this test remains a controversial issue (Vis, 2002). An issue of concern is that PSA is increased not only in the case of prostate cancer, but PSA concentration may be affected by other conditions such as prostatitis, benign prostatic hyperplasia (BPH), ejaculation, prostate gland biopsy or surgery (Frankel et al., 2003; Lai et al., 2003; Mackie, 2010). The US Preventive Services Task Force (USPSTF) also

found PSA screening detect other cases such as prostatitis besides prostate cancer (Harris & Lohr, 2008).

PSA has a poor specificity (American Urological Association, 2000; Lai et al., 2003; Mackie, 2010; Schmid et al., 2004). The cumulative of 7-years risk of being diagnosed with prostate cancer in a screening program based on PSA measurement reported the following findings (Aus et al., 2004): (i) 43 percent with PSA value between 3 to 6 ng/ml, (ii) 44 percent with PSA value 6 to 10ng/ml; and (iii) 71 percent with PSA value more than 10 ng/ml. PSA also gave false positive result (American Urological Association, 2000; Harris & Lohr, 2008; Mackie, 2010). It affected 76 percent of men in a screening trial (Ilic et al., 2006). Since 1989, the static and dynamic concepts have been developed to improve the specificity of PSA to avoid unnecessary biopsies (Schmid et al., 2004). The static concept include: PSA density (PSAD), PSA density of transition zone (PSAT), age specific reference range and ratio of free/total PSA and the dynamic concept include PSA velocity (PSAV) and PSA doubling time (PSADT).

The more frequent screening of prostate cancer, the greater is the quality adjusted life years (QALYs) (Baker et al., 2008). For repeat screening, the loss of QALY ranged from 1.1 to 1.4 (Baker et al., 2008). The American College of Physicians published a summary of the discussions held with men coming for prostate cancer counseling (Harris & Lohr, 2008): (i) prostate cancer is an important health problem; (ii) the benefit of one time or repeated screening and aggressive treatment of prostate cancer have not yet been proven; (iii) digital rectal examination and PSA measurement can have both false-positive and false-negative results; (iv) the probability that further invasive evaluation will be required as a result of testing is relatively high; (v)

aggressive therapy is necessary to realize any benefit from the discovery of a tumour; (vi) a small but finite risk for early death and a significant risk for chronic illness particularly with regard to sexual and urinary function are associated with these treatments; (vii) early detection may save lives; and (viii) early detection and treatment may avert future cancer-related illness.

2.1.9 Diagnosis and Investigations

PSA determination in conjunction with digital rectal examination are recommended in majority of clinical guidelines for early detection of prostate cancer (Schmid et al., 2004). The diagnosis of prostate cancer as confirmed by biopsy involves a removal of small pieces of the prostate tissue for microscopic examination. Prior to the biopsy, several tools are used to gather more information about the prostate and the urinary tract which are : digital rectal examination (DRE), the prostatic specific antigen (PSA), trans-rectal ultrasound (TRUS) and needle biopsy (Baker et al., 2008; Heidenreich et al., 2008; Mackie, 2010; Wolf et al., 2010). The diagnosis depends on the presence of adenocarcinoma in the biopsied prostate tissue (Heidenreich et al., 2008).

2.1.9.1 Trans-rectal Ultrasound (TRUS) and Needle Biopsy

TRUS is an image of prostate gland and surrounding tissue that allows the clinician to examine for any abnormalities. The aim of biopsy is for prostate cancer detection (Baker et al., 2008). Systemic prostate gland biopsy under ultrasound guidance is a preferred diagnostic method (Heidenreich et al., 2008). Ultrasound-guided trans-rectal, laterally directed 18G core biopsy become the standard way to obtain material for histo-

pathological examination. At least ten biopsy cores are needed or the use of the Vienna nomograms have been recommended for routine use (Heidenreich et al., 2008). The abnormal ultrasonic features include hypo-echoic areas, loss of differentiation of zones, asymmetry and capsular distortion (Kumar & Anderson, 2002).

2.1.9.2 Gleason Score

There are several grading systems described for prostate cancer and the Gleason system is the best (Kumar et al., 2005). The score used in the Gleason system is based on the architectural appearance of the prostate gland (Bracarda et al., 2005; Epstein, 2006). According to the Gleason system, prostate cancer can be stratified into five grades based on the glandular patterns and degree of differentiation (Bracarda et al., 2005; Kumar & Anderson, 2002). Grade 1 represents the most well differentiated tumour. The neoplastic glands are uniform and round in appearance and packed into well circumscribed nodules. In contrast, Grade 5 tumours show no glandular differentiation and the tumour cells infiltrate the stroma in the form of cords, sheets and nests. The other grades fall in between Grade 1 and Grade 5 (Bracarda et al., 2005; Epstein, 2006; Kumar et al., 2005).

Histologically, prostate cancer is classified into two grades. The primary grade describes the dominant pattern and a secondary grade describes the subdominant pattern. Then, the two numeric grades are added to obtain a combined Gleason grade or score (Bracarda et al., 2005; Epstein, 2006). A Gleason sum score ranges from two to ten and it is essential for treatment planning and decision-making (Heidenreich et al., 2008). Grading in prostate cancer is very important because it is the best marker, along

with the stage for predicting prognosis (Bracarda et al., 2005; Kumar et al., 2005). The descriptions of the Gleason grade of the prostatic cells are shown in Figure 2.3. The histologic grade is an important prognostic factor for survival estimation and for conservative treatment of localized prostate cancer. The 15-years mortality rate increases from four percent to seven percent for well differentiated tumours and from 60 percent to 87 percent for those with poorly differentiate tumours (Albertsen, Hanley, Gleason, & Barry, 1998).

	Gleason Scale	Description	Differentiation
	**1**	The cancerous prostate closely resembles normal prostate tissue. The glands are small, well-formed, and closely packed.	Well differentiated
	**2**	The tissue still has well-formed glands, but they are larger and have more tissue between them.	
	**3**	The tissue still has recognizable glands, but the cells are darker. At high magnification, some of these cells have left the glands and are beginning to invade the surrounding tissue.	
	**4**	The tissue has few recognizable glands. Many cells are invading the surrounding tissue.	
	**5**	The tissue does not have recognizable glands. There are often just sheets of cells throughout the surrounding tissue.	Poorly differentiated

Figure 2.3: The Gleason Scale and its description.
Source: adapted from http://en.wikipedia.org/wiki/Gleason_score

2.1.9.3 Staging

Staging for cancer cells tells us how far the cancer has spread. It helps in making decisions regarding treatment (American Urological Association, 2000; Cancer Research UK, 2010). Prostate cancer tends to spread to the bones rather than any other organs (Cancer Research UK, 2010). Staging for prostate cancer is important in the selection of the appropriate form of therapy. Staging procedure can be derived from the same tools that lead to the bioptic diagnosis of the disease (i.e TURP and PSA) and partly from imaging techniques such as X-ray, abdominal CT or MRI and radionuclide bone scan (Bracarda et al., 2005).

The most common staging system is TNM system proposed by the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer 2002 (UICC) (American Cancer Society, 2011; American Urological Association, 2000; Bracarda et al., 2005). T stage is determined by DRE, TURP and TRUS biopsy. The N and M stages are determined by a combination of clinical examinations, blood tests and imaging CT, MRI and bone scan (Mackie & Rai, 2008).

Regional lymph nodes are the nodes of true pelvis below the bifurcation of the common iliac arteries (Bracarda et al., 2005). Any spread of tumour to these lymph nodes, regardless of extent is eventually associated with a fatal outcome. The staging system merely records the presence or absence of this finding (N0/N1) (Kumar et al., 2005). Any metastases to more than one site are considered as metastases are present (M1). M1c is a category for the most advanced metastases (Bracarda et al., 2005).

Table 2.4 shows the prognosis of prostate cancer related to tumor stage. Patients with stage B(T2) or higher disease have a hard nodule on the prostate during per-rectal examination and over 60 percent of these patients experience urinary retention or urinary infection due to obstruction (William et al., 2003).

Table 2.4: Treatment and prognosis of prostate cancer related to tumor stage

Conventional stage	TNM stage	Clinical Finding	Treatment	Fifteen-Year Survival (%)
A1	T1a	Non palpable, incidental finding at prostatectomy (low grade cancer seen in <5 % of prostate)	Observation	Normal
A2	T1b	Same as above except tumour is high grade, or >5% of prostate is involved, or both	Total prostatectomy with pelvic lymphadenectomy	30 – 45
B1	T2a	Localized nodule 1 – 1.5 cm in diameter in one lobe		50 – 60
B2	T2b	Tumor is ≥1.5cm in diameter or in more than one lobe		35 – 45
C	T3, T4	Periprostatic extension	Radiation with or without pelvic lymphadenectomy	20 – 30
D	N+ or M+	Pelvic lymph nodes involvement or distant metastases	Hormonal therapy (orchidectomy or LHRH / antiandrogen) when symptomatic. Irradiation for isolated bone pain	0 -10

Adapted from Richard et al., (2003)

2.1.9.4 Prognosis

The prognosis of prostate cancer depends on the degree of histologic differentiation and the tumour itself. Histologically, most of the lesions are adenocarcinoma with varying degrees of differentiation (Kumar et al., 2005). Besides clinical staging, the most significant prognostic factors are the initial (pre-therapeutic) level of total PSA and the Gleason score. Recent studies introduced new prognostic markers to increase the accuracy of prognosis prediction. The new prognostic markers were the genetic markers, the apoptosis index and micro-vascular density (Bardan et al., 2007).

Gleason score is often combined into groups with similar biologic behaviour (Kumar et al., 2005): (i) two to four representing well differentiated cancer; (ii) five to six representing intermediate grade cancer; (iii) seven representing moderate to poorly differentiated; and (iv) eight to ten representing high-grade cancer. It is correlated better with prognosis than the single Gleason grade (Bracarda et al., 2005; Kumar et al., 2005).

Predictive factors for localized prostate cancer are PSA, Gleason score, operative prostate biopsy findings, pre-operative data and clinical stage (Kumar et al., 2005). However the prognosis does not change significantly with therapy choices for localised disease (surgery, EBRT, brachytherapy or watchful waiting). The patients should be informed about the potential hope including ongoing care that the patients will receive and the clinician should assess the patients concerning personal prognosis (Rodin et al., 2009).

2.1.10 Impact on Diagnosis

It was indicated that screening is not clinically significant for prostate cancer diagnosis (Brawley, Ankerst, & Thompson, 2009). The American Cancer Society recommends that PSA and digital rectal examination should be offered annually beginning at age 50 to men (American Cancer Society, 2011; Smith et al., 2003). Men with important risk factors, prostate cancer testing beginning at age 45 and digital rectal examination should be part of prostate testing. Those who have abnormal findings should undergo transurethral resection biopsy for definitive diagnosis (Smith et al., 2003).

2.1.10.1 Impact on Incidence of Prostate Cancer

The incidence of prostate cancer increased due to the effect of screening of PSA level (Brawley et al., 2009; Hankey et al., 1999). The incidence increased sharply in the late 1980s following an introduction of Prostate Specific Antigen (PSA) screening test (Kumar et al., 2004; Mackie & Rai, 2008; Sartor & Loriaux, 2006). From the SEER program, it was shown that the incidence of prostate cancer in US increased steadily during the 1980s by 85 percent between 1987 and 1992 and reached an adjusted value of 190.1 per 100,000 populations. However the incidence subsequently decreased by 29 percent between year 1992 to 1996 (Ries et al., 2008; Sarma & Schottenfeld, 2002).

2.1.10.2 Impact on Stage of Prostate Cancer

The screening for prostate cancer has an impact on the staging of the tumour. Figure 2.4 shows the age adjusted incidence of prostate cancer in White population by stage of the tumour.

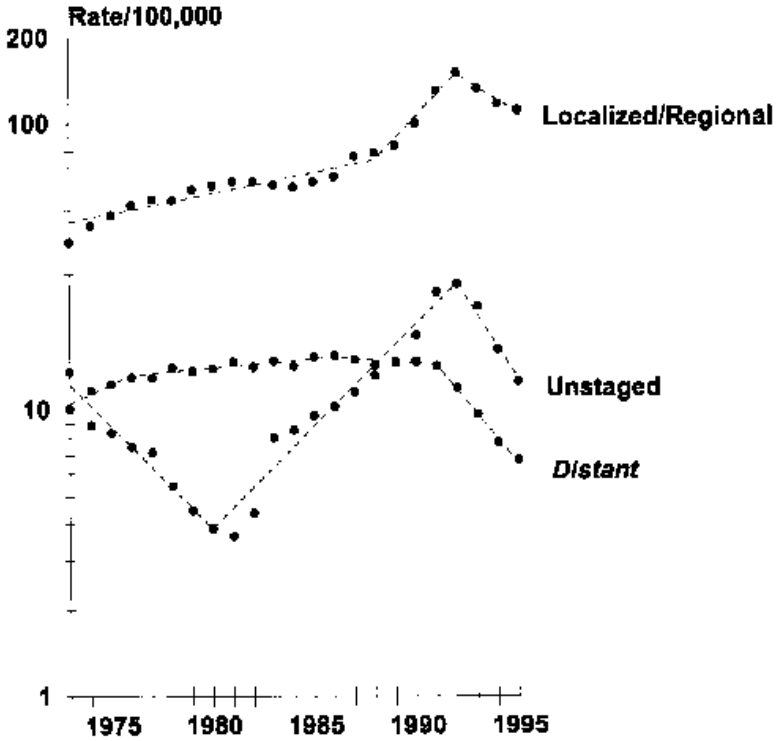


Figure 2.4: Age adjusted (1970 US standard) prostate cancer incidence in White population by stage (Hankey et al., 1999).

Before introduction of PSA, in the mid 1980's, it was observed that there was a decrease for un-staged prostate cancer. Meanwhile, there was an increase for staged prostate cancer in the same period. However, the reports were not correct due to misinterpretation of coding instructions. Starting in 1988 after introducing PSA screening, the localized/regional stage increased the annual percent change (APC) by 18.7 percent and un-staged increased APC by 17.9 percent. However, the distant

stage decreased by 1.3 percent. After year 1992, all the stages were decreased by 9.8 percent APC in localized and regional stages, 17.9 percent APC in distant stage and 22.5 percent APC in un-staged (Hankey et al., 1999)

2.1.10.3 Impact on Grade of Prostate Cancer

Screening also gave an impact on the grade of the prostate cancer. Figure 2.5 shows the age adjusted prostate cancer incidence in White population in US by tumor grade.

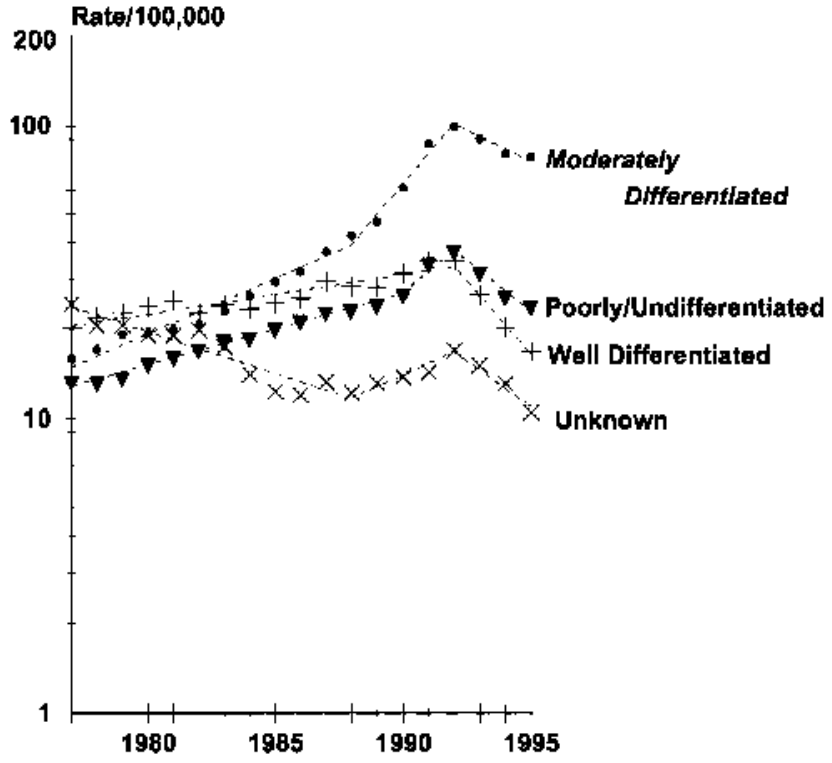


Figure 2.5: Age-adjusted (1970 US standard) prostate cancer incidence in White by tumour grade (Hankey et al., 1999)

It showed that due to screening, the incidence of moderately differentiated tumour increased the overall incidence trend with an annual percent change (APC) by 0.1

percent from 1977 to 1988. The APC increased to 26.9 percent starting 1988 and the trend decreased in 1992 with 9.3 percent APC. The patterns of poorly differentiated and undifferentiated tumours were almost similar to moderately differentiated tumours with 5.8 percent APC and 3.2 percent APC from 1975 to 1992. However, the trend began to decrease by 20.4 percent APC for well differentiated tumour and 14.7 percent APC for poorly differentiated and undifferentiated tumours (Hankey et al., 1999).

2.1.10.4 Impact on Mortality

There are no conclusive data to confirm that early detection decreased mortality of prostate cancer (Hsing, Taso, & Devesa, 2000)**.** Screening alone is not the only cause for the decline in prostate cancer mortality over the past 15 years (Brawley et al., 2009). The potential confounding influence for treatment pattern change and mis-attribution bias make a definitive conclusion about the link between PSA screening and mortality rates (Potosky, Feuer, & Levin, 2001). The decrease in prostate cancer mortality, occurring just few years after the implementation of screening is very difficult to attribute to screening per se when dealing with a disease with a long natural history (Brawley et al., 2009)**.**

Data from SEER program shows the mortality rate gradually increased from 1976 from 22.1 per 100,000 to 26.7 per 100,000 in 1992. However it decreased through 1997 to 15.9 per 100,000 (Ries et al., 2008). It was observed that the decrease of the mortality was mainly due to a reduction of death from distant disease (Sarma & Schottenfeld, 2002)**.** From the registry, the data suggested that screening may account

for 45 percent to 70 percent of the observed decline in mortality (Brawley et al., 2009).

Report from the European Randomised Study of Screening for Prostate Cancer (ERSPC) showed a reduction of death rate in screening group compared to the control group for 0.8 (95%CI: 0.65 – 0.98) (Schröder et al., 2009). However, in the US study, Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial showed no statistically significant difference in death rate (Eckersberger et al., 2009). Meta-analysis of five randomized control trials (RCTs) with a total of 341,351 participants also showed no significant difference in prostate cancer-specific mortality between randomized to screening and control group (RR:0.95, 95% CI: 0.85 – 1.07) (Ilic et al., 2006).

Benefits from the screening may take up to 10 years to accrue so that a man who have a life expectancy less than 10 to 15 years should be informed that the screening for prostate cancer is unlikely to be beneficial (Ilic et al., 2006). The lack of data regarding whether PSA screening decreases the risk of death makes quality of life issues related to treatment very important in the decision-making process regarding whether to be screened or not (Brawley et al., 2009).

2.2 Depression, Anxiety and Stress in Prostate Cancer Patients

Prostate cancer patients face several barriers to receive an appropriate psychiatric intervention and tend to underestimate the psychological co-morbidity. It may remain untreated even after identification. Sexual dysfunction carry a greater social stigma that mostly affect prostate cancer patients (Kunkel et al., 2000). Urinary incontinence, sexual dysfunction and fatigue are major emotional and physical stressors among prostate cancer patients. Prostate cancer patients must cope with psychological issues for long term cancer survivorship (Kunkel et al., 2000). Prostate cancer patients reported greater levels of social and emotional problems as well as insomnia, constipation and diarrhoea compared to the general population (Zenger et al., 2010). Issues related to relationship and intimacy are important for psychological adjustment for early stage prostate cancer survivors and their partner (Manne, Badr, Zaider, Nelson, & Kissane, 2010).

2.2.1 Depression

2.2.1.1 Introduction

Depression is a normal response to loss or misfortune called grief or mourning. However, depression is abnormal when it is out of proportion to the misfortunes or is unduly prolonged (Gelder, Harrison, & Cowen, 2006)**.** Depression can occur in any psychiatric disorder and the symptom of depressed mood is a component of many psychiatric syndromes and is commonly found in certain physical diseases (Gelder et al., 2006; World Health Organization, 1992, 2007). In general, the prevalence of

depression for women ranges from five percent to 12 percent, while among men it ranges from two percent to three percent (Massie, 2004).

Depressive disorders are syndromes that are concerned with depressed mood. It is associated with central features of depressed mood, negative thinking, lack of enjoyment, reduced energy and slowness that has been categorized in a wider section of "Mood Disorder" (American Psychiatric Association, 2000; Gelder et al., 2006)**.** Scientists believe that depression has a biochemical basis. It reflects imbalances between neurotransmitters and hormones that affect how the brain functions. Researchers found decreased levels of serotonin and dopamine in the brain of people who have chronic or severe depression (Rothfeld & Romaine, 2005)**.** It most likely represents a complex combination of the elements of psychodynamic, cognitive, genetic, neuroendocrine and neurotransmitter determinants (Worthington & Rauch, 2009)**.** Depression due to cancer pain is not associated with age (Gagliese, Gauthier, & Rodin, 2007).

Common symptoms of depression in men includes (Rothfeld & Romaine, 2005): (i) inability to control or influence events and circumstances, coupled with feelings and expressions that others are to be blamed; (ii) compulsive and demanding of others and provoke confrontation and discord; (iii) irritability, frustration and frequent outbursts of anger that manifest as arguments, physical fights and road rage; (iv) wreckless and destructive behaviours such as increased alcohol consumption, substance abuse and high risk sexual encounters; and (v) actions and behaviors intended to prove personal strengths and thinking about, talking about or attempting suicide. Depression

diagnosis itself can increase psychological suffering and mortality rates (Massie, 2004).

The comorbidity of major depression associated with a barrier to treatment and worse psychiatric outcomes, including treatment resistance, increased risk for suicide, greater chance for recurrence and greater utilization of medical resources (Aina & Susman, 2006). Multi-component interventions are potentially feasible in treatment of depression in patients with cancer and can be perceived by patients as less stigmatizing than referral to a mental-health specialist (Rodin, 2008).

2.2.1.2 Depression and Prostate Cancer

Men with prostate cancer have higher rates of depression compared to men in the general population (Hinz et al., 2009; Korfage, Essink-Bot, Janssens, Schroder, & de-Koning, 2006; Nelson et al., 2009a). Study by Walker et al., (2007) found the prevalence of depression among prostate cancer patients was 8.2 percent which was lower compared to depression among psychiatric outpatients (24 percent) (Matsudaira et al., 2009) and patients who attended to general practice [18.5 percent (95% CI: 16.5 – 20.6] (Olssøn, Mykletun, & Dahl, 2005). Meanwhile, prostate cancer patients have lower depression rate compared to other cancer patients (Massie, 2004).

Prostate cancer patients experience levels of depression elevated above those of their fellows, with a greater incidence of clinically significant depression overall than men without prostate cancer (Sharpley et al., 2008). However, the percentage of depression among prostate cancer patients reduced from 24 percent to 12.5 percent from the time of diagnosis to the time of survey (Sharpley & Christie, 2007b).

Depression in prostate cancer patients is closely related to melancholia. The stronger presence of melancholia in the depressive symptomatology in prostate cancer patients suggest that some forms of treatment for depression may be more likely to succeed than other psychological problems (Sharpley, Bitsika, & Christie, 2011). The mean depression scores of 5-year cohorts consistently trended upwards and greater symptoms were associated with aging (r= 0.18, p<0.01) (Nelson et al., 2009a). PSA levels of prostate cancer patients showed small correlation with intrinsic religiousity (r=-0.23) and moderate correlation with spirituality (r=-0.58) (Nelson et al., 2009a).

Prostate cancer patients who receive treatment were also experiencing depression. Among those who were treated with radiotherapy, 27 percent reported significant levels of depression (Korfage et al., 2006) and those who had orchidectomy had a slightly higher risk for depressive disorder (RR= 1.15; 95% CI, 1.03 – 1.27) (Shahinian, Kuo, Freeman, & Goodwin, 2006). The risk for depressive disorders was 1.13 percent (95%CI: 1.08 – 1.19) among prostate cancer patients who received androgen deprivation compared to patients without cancer (Shahinian et al., 2006). However, hormonal therapy does not appear to cause significant depression among men with locally advanced prostate cancer. The rates for least mild depression arise from 10.4 percent to 16.3 percent over a period of 12 months but were not significantly different at each time point (Pirl, Greer, Goode, & Smith, 2008).

2.2.1.3 The Impact of Depression on Quality of Life

Many studies found that depressive symptoms were related to survival time and quality of life (QOL) including functional status after a cancer diagnosis. The

proportion of patients with clinically severe impairment in QOL varies with different diagnoses with 63 percent in major depressive disorder, 85 percent in chronic and double depression (Rapaport, Clary, Fayyad, & Endicott, 2005).

Acute leukemia patients who underwent allogenic bone transplantation and had depression were found to have poorer outcome and shorter duration of survival (Colon, Callies, Popkin, & McGlave, 1991). Among lung cancer patients, the functional status was the risk factor for depression which increased by 41 percent for each increment on the impairment scale (Hopwood & Stephens, 2000). Depression explained an additional 10 percent of the variance among Parkinson's disease (Hanna & Cronin-Golomb, 2012). Among Human T-cell lymphotrophic virus type I (HTLV-1) patients, the main factors that correlated with level of depression and the associated factors for QOL were education, family income and social class (Gascón et al., 2011).

In cancer patients who underwent chemotherapy, the symptoms and psychological variables explained 47 percent of the variance in QOL with the largest proportion of the variance was due to depression (Redeker, Lev, & Ruggiero, 2000). Depression could also be a risk factor of insomnia among prostate cancer patients treated with radical prostatectomy (Savard et al., 2005) and was significantly correlated with pain consistency (r=0.32, p=0.001) and pain permanence (r=0.3, p=0.003) (Tavoli, Montazeri, Roshan, Tavoli, & Melyani, 2008). Patients with pain had significantly higher levels of depressive symptoms compared to patients in the pain free group (Glover, Dibble, Dodd, & Miaskowski, 1995; Tavoli et al., 2008).

Depression emerged as the only independent risk factor in unexplained chest pain among women (Fagring et al., 2008). Depressive symptoms were strongly associated

with greater symptom burden [OR: 1.8 (95% CI: 1.3 – 2.7), p=0.002], greater physical limitation [OR: 3.1 (95% CI: 2.1 – 4.6), p<0.001], poor quality of life [OR: 3.1 (95% CI: 2.2 – 4.6), p<0.001), and poor overall health (OR: 2.0 (95% CI: 1.3 – 2.9), p<0.001] (Ruo et al., 2003).

Depression status affects the financial status of the patients. In 1990, the total health care costs of mental disorders amounted to US$147.8 billion (Rice & Miller, 1998). In 445 medical inpatients, 27.9 percent was identified as very depressed giving rise to 35 percent greater mean of hospital cost and care services and 40 percent longer mean length stay in the hospital (Levenson, Hamer, & Rossiter, 1990). The overall visit length increased among depressed patients (Callahan et al., 1996). In Canada, a diagnosis of prostate cancer carried a significant burden and like other cancers was a cause of significant depression (Fradet, Klotz, Trachtenberg, & Zlotta, 2009).

2.2.2 Anxiety

2.2.2.1 Introduction

Anxiety is a state of apprehension, uncertainty and fear arising from the anticipation of a realistic or imagined threatening event and it often impairs physical and psychological functioning. The International Classification of Disorders (ICD) and other classification systems used in psychiatry require a core of anxiety symptoms manifesting autonomic over activity to be present (American Psychiatric Association, 2000). Anxiety disorder is abnormal, causing disruption such as emotional distress or disruption of functioning (World Health Organization, 2007).

Anxiety is a normal response to danger, however it becomes abnormal when its severity is out of proportion to the threat of danger or when it outlasts the threat (Gelder et al., 2006). The physical symptoms of anxiety may include increased heart rate and breathing, tightness of muscles, restlessness, exercise perspiration, fatigue and headaches (Smith, 1993). Anxiety can be chronic (extended over time) or episodic (related to specific circumstances) and each has a range of symptoms (Rothfeld & Romaine, 2005). Roy-Byrne et al., (1995) classified the feature of anxiety into apprehensive expectation, vigilance, motor tension and autonomic hyperactivity.

Maynard et al., (1995) classified anxiety into cognitive and somatic. The cognitive anxiety is the mental aspect that involves negative thought patterns (Maynard et al., 1995) or a mental component of anxiety and is caused by negative expectations about success or by negative self-evaluation (Rainer, Robin, & Damon, 1990). Meanwhile, somatic anxiety is the psychological component of anxiety that involves autonomic arousal (Maynard et al., 1995) or the physiological and affective elements of the anxiety experience that develop directly from autonomic arousal (Rainer et al., 1990). The American Psychiatric Association (2000) identified pathological anxiety as: (i) being out of proportion to the level of threat; (ii) persistence or deterioration without intervention; (iii) symptoms which are unacceptable regardless of the level of threat; and (iv) disruption of usual or desirable functioning.

Anxiety disorders play an important role in terms of risk, co-morbidity and outcome (Roy-Byrne et al., 2008). Moreover, anxiety disorders are strongly and independently associated with chronic medical illness, low levels of physical QOL and physical

disability (Sareen et al., 2006). In the general population the younger people (Mayou & Hawton, 1986), women (Khan et al., 2007; Mayou & Hawton, 1986), physical illness (Khan et al., 2007) and people in lower socioeconomic groups are at risk of anxiety (Mayou & Hawton, 1986).

Anxiety does not occur as a single phenomenon. Spielberger (1966) introduced the concept of anxiety by distinguishing Trait-anxiety and State-anxiety. Both of these anxieties are multidimensional construct (Endler & Kocovski, 2001; Endler, Parker, Michael, & Cox, 1991) and it could be conceived as an analogue in certain concepts of potential energy and kinetics in physics (Ricardo, 1966).

The overlapping between anxiety, depression and chronic stress states suggests that the clinicians should broaden their search for mental health problems beyond depressive symptoms in their patients with chronic medical illness to include symptoms of anxiety (Roy-Byrne et al., 2008). Measuring anxiety is useful in understanding the relationship between level of arousal and (in)effective decision making strategies (Bekker, Legare, Stacey, O'Connor, & Lemyre, 2003). The relationship between anxiety is further strengthened due to their common patho-physiological pathway, shared causal linkages to worry, prolonged arousal, lowered immune functioning, fatigue and low-level infections and the feelings of helplessness and pessimism that the future will offer any respite (Barlow & Durand, 2005).

2.2.2.2 Anxiety in Cancer Patients

Anxiety symptoms are common in cancer patients (Stark et al., 2002; Stark & House, 2000). Receiving a cancer diagnosis may lead to anxiety which adversely influence

these men's relationships with others (Kunkel et al., 2000). Anxiety symptoms levels are high soon after the onset of cancer but reduce over time (Fallowfield, Hall, Maguirev, Baum, & A'Hern, 1994).

Anxiety can be one aspect of the physiological reaction to advanced disease and may be present at a clinical level. It can hinder or even prevent the diagnosis and management of other problems. When it develops into an anxiety state, it can be disabling (Mahuire et al., 1995). An increase in anxiety level is linked with breaking bad news and physicians should be aware of these influences (Lie´nard et al., 2006). There was a weaker association between demographic parameters and psychiatric morbidity previously noted in the presence of physical illness (Stark et al., 2002).

The prevalence rates of anxiety disorder among cancer patients was 10 – 30 percent which was greater than those of depression in many cases (Roy-Byrne et al., 2008; Stark et al., 2002). The prevalence varies with the type and stage of cancer, treatment regimens, time since diagnosis, gender and methods used to diagnose psychiatric illness (Roy-Byrne et al., 2008).

2.2.2.3 Anxiety and Prostate Cancer

Prostate cancer patients were more likely to suffer anxiety disorder than men in the general community (Couper et al., 2006; Hinz et al., 2009). However, the anxiety decreased significantly with subsequent rounds of examination and with increasing age (Carlsson, Aus, Wessman, & Hugosson, 2007; Nelson et al., 2009b). The mean anxiety level is clinically reduced from the time of diagnosis (20 percent) to the time of survey (12 percent), where it is associated with reductions in psychomotor

function, agitation, weakness, fatigue and pessimism (Sharpley, Bitsika, & Christie, 2007). The prevalence was 28 percent among prostate cancer patients classified as 'high-anxiety' before the treatment and their anxiety scores decreased significantly post-treatment (Korfage et al., 2006). Low levels of anxiety among prostate cancer patients demonstrates their ability to cope with the diagnosis and management of malignant disease (Wilkinson, Warren, Ramsden, Matthews, & Chodak, 2008).

Anxiety in prostate cancer is not only associated with initial diagnosis but also as part of the ongoing disease process (Wilkinson et al., 2008)**.** Prostate cancer patients experience elevated levels of anxiety above those of their fellows, with a greater incidence of clinically significant anxiety overall than men without prostate cancer (Sharpley et al., 2008). They were associated with the effective decision strategies and stressful health intervention (Bekker et al., 2003). Aging was also related to less anxiety (r=-0.22) in prostate cancer (Nelson et al., 2009b).

2.2.2.4 The Impact of Anxiety on Quality of Life in Cancer Patients

Patients may experience psychological anxiety at the time of diagnosis, before and during the treatment and over a period of time as they adjust to the changes with the treatment (National Cancer Institute, 2011; Rapaport et al., 2005). Anxiety may impair the QOL of the patient's life as it may cause psychological and physical suffering, interferes with day to day functioning, delay in return to work and affect the relationships and decision making (Maguire, 1997).

Higher levels of trait-anxiety were close and consistently related to poorer QOL in post-traumatic stress disease among rectal cancer patients. Each increase of 0.1 units

in the trait-anxiety score was associated with 28 to 56 percent increase in the probability of having a Functional Assessment of Cancer Therapy-Colorectal scale (FACT) score below the median (Ristvedt & Trinkaus, 2009). Parents with childhood cancer and brain tumour survivors had significant lower QOL (3.1 points lower; $p<0.01$) on the mental health component summary score of the SF-12, which were completely mediated by perceived anxiety (Witt et al., 2010).

A diagnosis of cancer also carries a significant burden due to significant anxiety (Fradet et al., 2009). The patient's economy was also affected due to anxiety. A study in the US in 1990 found that anxiety disorders treatment cost to be approximately $42.3 billion, or $1542 per sufferer (Greenberg et al., 1999). Among medical inpatients, 27.5 percent were identified as very anxious due to concerns regarding the cost of medical care services (Levenson et al., 1990) and 88 percent was attributable to loss of productivity while at work as opposed to absenteeism (Greenberg et al., 1999).

2.2.3 Stress

2.2.3.1 Introduction

Stress is defined as an imbalance between perceived environmental demand and one's perceived response, which could result in important consequences (Rainer et al., 1990). Stress results when an individual is not able to handle a situation because of a lack of coping resources (Peter, 1992).

The word "stress" was first used by psychologist, Hans Selye in the 1930 that defined stress as a general pattern of arousal response involving a number of neuro-endocrine

mechanisms whose chronic activation ultimately led to an 'exhaustion' of the organism and an inability to cope with further challenge (Evans, 1991; Selye, 1976). It is related to both external factors including physical environment, job, relationship with others in all situations, challenges, difficulties, expectations and internal factors that influence our abilities to handle stress including nutritional status, overall health and fitness levels, emotional well-being and the amount of sleep and rest (Payne, 2000; Rothfeld & Romaine, 2005; Sonnanburg, 2005).

Stress is part of the heritable and half of them is due to genetic factor (Federenko et al., 2006). The high levels of familial risk for psychosis is associated with high levels of emotional reactivity to daily life stress in a dose-response fashion (Myin-Germeys, Os, Schwartz, Stone, & Delespaul, 2001). The transactional model of stress postulates that stress occurs as a result of an interaction between personal and environmental factors (Lazarus & Folkman, 1984**).** According to the transactional model of stress, the physical, affective, cognitive and behavioural domains are all inter-related and thus when a change occurs in any one of them, the other domains are also affected (Peter, Rikk, & Murray, 1988).

An individual's stress response is determined by three factors (Mark & Jean, 1988): (i) personality characteristics such as hardiness, locus of control, anxiety traits, achievement motivation and sensation seeking may contribute to the stress response; (ii) a person's history of stressors, including major and minor life events, will affect his or her stress response; and (iii) coping resources and social support that an individual can rely on will also be influential. The severity of mental illness depends on how the individual perceives stress (Bailey & Bailey, 1997). The factors that

contribute to the experience of stress include cognitive appraisal and coping resources (Peter et al., 1988). Physiological reaction to stress involves symptoms associated with increased arousal, such as increased heart rate, sweating, dizziness and muscle tension. The cognitive component of stress involves distorted thinking and poor concentration, while the affective stress response may include worry, aggression, fear, anger and sadness (Sonnanburg, 2005).

2.2.3.2 Stress Responses

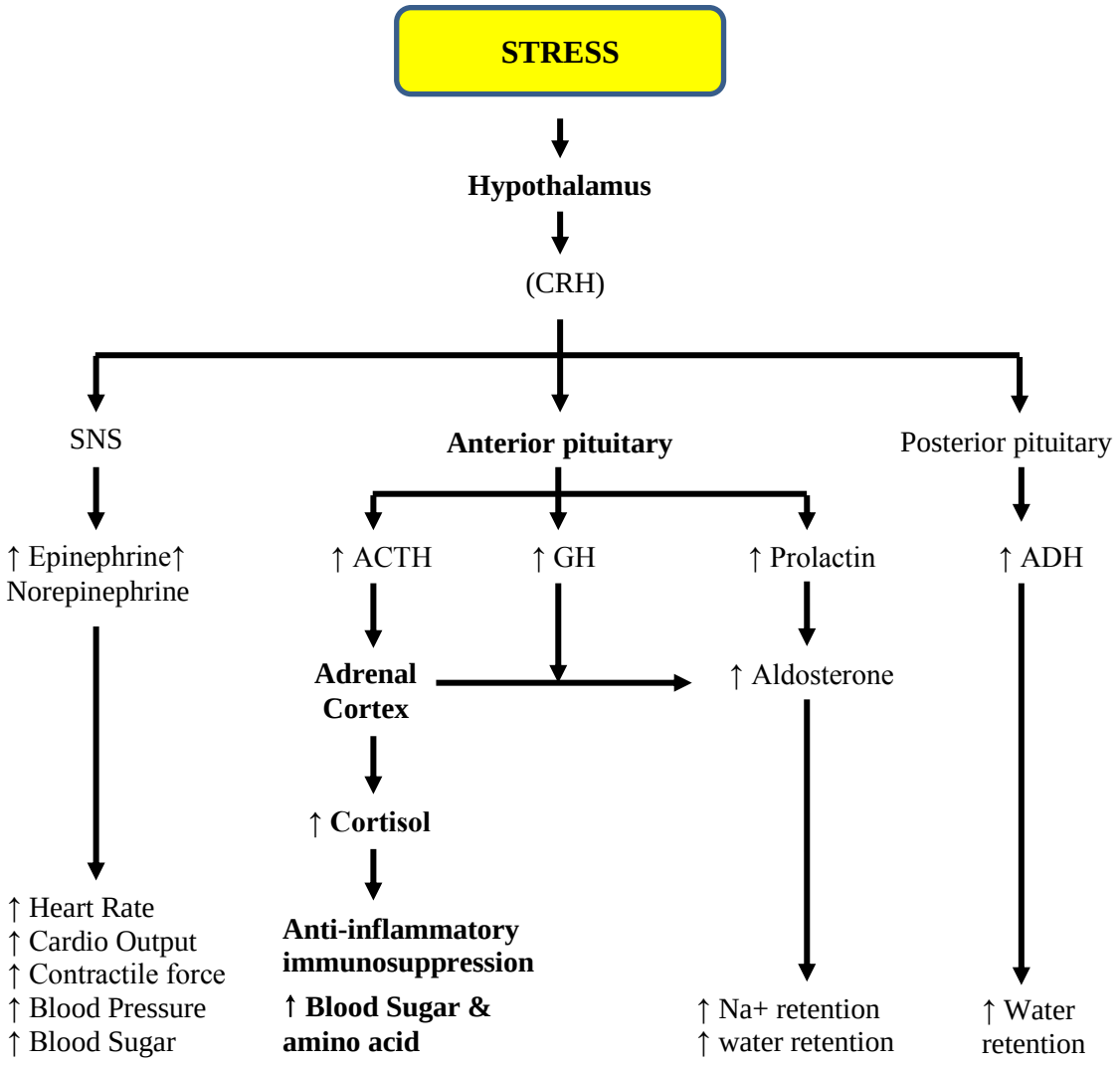
Stress response is a physiologic response consisting three phases (Selye, 1946). The first phase is a "fight-or-flight" response where the sympathetic nervous system is activated. Second phase is where the organism adapts to the source of stress and the last phase is exhaustion. All the phases are also called general adaption syndrome.

Stress consists of the biological/physiological and psychological stress responses. Physiological stress response was measured by levels and circadian pattern of saliva cortisol. Meanwhile, psychological stress response is represented by perceived stress (Selye, 1976). The stress responses involved the same chain of events and the same pattern of psychological correlates in the situational context or physiological interpretation of a demanding situation (Selye, 1976).

2.2.3.2.1 Physiological Stress Response

Physiological stress response is defined as chemical or physical disturbance in the cells or tissue fluid produced by a change either in the external environment or within the body itself (Selye, 1946). It is initiated when a stressor is present in the body or

perceived in the mind. In this response, it involves the sympathetic branch of the nervous system (notably the brain, the autonomic nervous system and the somatic nervous system), the endocrine system (especially pituitary and adrenal glands) and the immune system (including the lymph nodes and certain cells in the blood) (Maddock & Pariate, 2001; Segerstom & Miller, 2004; Sonnanburg, 2005). Interaction among brain, pituitary and the adrenal glands (i.e. the hypothalamic-pituitary-adrenal (HPA) axis) help to regulate the body's response to stress by maintaining the body's dynamic steady state (Adinof, Iranmanesh, Veldhuis, & Fisher, 1998). The pathway of the physiological response to stress is shown in Figure 2.



CRF = corticotrophin-releasing factor; SNS = sympathetic nervous system; ACTH = Adrenocorticotropic hormones; GH = Growth hormone; ADH = Antidiuretic hormone; Na+ = natrium

Figure 2.6: The pathway of physiological stress response (Shelby & McCance, 2001)

The physiological stress response is activated by the sympathetic nervous system from the brain and the endocrine system. In response to stress, the hypothalamus produces corticotrophin releasing hormone (CRH) and/or arginine-vasopression (AVP) and stimulates the release of adrenocorticotrophic hormones (ACTH) from the

pituitary gland (O'Connor, O'Halloran, & Shanahan, 2000). The ACTH arrives at the adrenal cortex via the bloodstream and stimulates cortisol release (Adinof et al., 1998). The cortisol is also produced due to neuroendocrine response to stress after stimulation of the adrenal medulla to secrete catecholamines (epinephrine and norepinephrine) and stressor-induced stimulation of the pituitary to secrete ACTH, that stimulates the adrenal cortex cortisol (Maddock & Pariate, 2001; McComb, 2001; Shelby & McCance, 2001).

Another pathway involves cortisol production during physiological stress response. When the sympathetic nervous system is aroused, it causes the medulla of the adrenals to release catecholamines (epinephrine, norepinephrine and dopamine) into the bloodstream. Simultaneously, corticotrophin-releasing hormone (CRH) stimulates the pituitary gland to release a variety of hormones, including anti-diuretic hormone (ADH), from the posterior pituitary gland; and prolactin, growth hormone and ACTH from the anterior pituitary gland. ACTH stimulates the cortex of the adrenal gland to release cortisol (McComb, 2001; Shelby & McCance, 2001).

Stress affects cognition in a number of ways which acts via catecholamines (Greenberg, Carr, & Summers, 2002; McEwen & Sapolsky, 1995). The catecholamine is released to prepare the body to act on the cardiovascular system. Epinephrine increases cardiac output and dilates the blood supply to the heart, brain and skeletal muscles and dilates the airways thereby increasing the delivery of oxygen to the blood stream (Chrousos & Gold, 1992). However, epinephrines constrict the blood vessels of the viscera and skin that shift blood flow to the vessels dilated by

epinephrine. Meanwhile, norepinephrine increases the mental alertness (Maddock & Pariate, 2001; McComb, 2001; Shelby & McCance, 2001).

Growth hormone (GH) and prolactin (PRL) are the other hormones which are released during physiological stress response where CRH suppresses growth function (Tsigos & Chrousos, 2002). PRL is for the breast development and lactation; meanwhile growth hormone is involved in tissue repair and participates in growth. During physiological stress, aldosterone is secreted at the adrenal cortex by ACTH and ADH is released from the posterior pituitary gland. Both aldosterone and ADH stimulate water retention and increase fluid volume in the body (Shelby & McCance, 2001).

2.2.3.2.2 Psychological Stress Response

There was no consistent definition of psychological stress response. However, Stone et al., (1999) defined psychological stress response as an experience of negative events or the perceptions of distress and negative effects associated with the inability to cope with them. It may include perception, appraisal and coping with situations an individual encounters. Lazarus and Folkman (1984) developed a transactional model where there were three main components in that model which were: stress, appraisal and coping. In this model, stress is defined as a relationship between the individual and the environment that is appraised by the individual as taxing the resources and endangering well-being.

The Perceived Stress Scale (PSS) was developed in 1983 to measure of the degree to which situations in one's life are appraised as stressful (Cohen, Kamarack, &

Mermelstein, 1983). PSS is based on the relationship between the person and environment. Sheldon et al., (1983) developed a global and event-specific measure of perceived stress which is based on how the person perceived or evaluated a situation as stressful or not stressful.

There was a relationship between psychological stress and the secondary immune response and weak primary immune response which was amplified among elderly and population with vulnerable immune system (Cohen, Miller, & Rabin, 2001). In attention-deficit hyperactivity disorder (ADHD) patients, they perceived greater difficulties in psychological recovery after cessation of the stressor (Lackschewitz, Huther, & Kroner-Herwig, 2008). Psychological stress in men is associated with an increase in cerebral blood flow in the right prefrontal cortex and a reduction of cerebral blood flow in the left orbito-frontal cortex. Meanwhile, in women the psychological stress primarily activates the limbic system, including the ventral striatum, putamen, insula and singulate cortex (Wang et al., 2007).

2.2.3.3 Stress and Prostate Cancer

Stress can affect an individual's disease (Petticrew, Fraser, & Regan, 1999). In prostate cancer patients, they are repeatedly exposed to potential stress and fear because of the requirement for continual PSA monitoring (Stone et al., 1999; Wilkinson et al., 2008). Low levels of stress among prostate cancer patients demonstrates the ability of patients to cope with the diagnosis and management of malignant disease (Wilkinson et al., 2008).

Oxidative stress is implicated in prostate cancer by several lines of evidence measured by the level of F2-Isoprostanes (F2IP) using gas chromatography/mass spectrometry. It was found that the adjusted geometric mean F2IP levels were higher in patients with prostate cancer (OR:1.82, 95% CI: 1.66 – 2.00) and high-grade prostatic intraepithelial neoplasia (HGPIN) (OR: 1.82, 95% CI: 1.68 – 1.96) than in controls (OR: 1.63, 95% CI: 1.49 – 1.78) (Barocas et al., 2011). African American prostate cancer patients had higher prevalence of traumatic stress compared to non-African American and the elevation remained across all time points over 24 months (Purnell et al., 2011). There was a significant interaction between social constraints and perceived stress (coefficient = 0.58, p=0.03). The significant interaction was found on intrusive thought and greater perceptions of stress among prostate cancer patients (Halbert et al., 2010b). However, Nielsen et al., (2007) found no differences in prostate cancer risk according to stress (HR = 0.99; 95% CI: 0.90 - 1.09). Job strain also did not shown any significant association for the risk of prostate cancer (hazard ratio: 0.86, 95%CI: 0.68 – 1.09) (Heikkilä et al., 2013)

Helping men cope with stress before prostate cancer surgery may speed up both their physical and psychological recoveries (Parker-Pope, 2011). Results indicated a positive social relationship contribute to improved quality of life in patients who had underwent treatment for localized prostate cancer. One pathway through social support that can benefit the quality of life is through lower perceptions of stress (Zhou et al., 2010). Stress reduction may result in reduction of central adiposity and improvement of the hormonal milieu of patients with recurrent prostate cancer (Saxe, Major, Westerberg, Khandrika, & Downs, 2008).

2.2.3.4 The Impact of Stress on Quality of Life

The association between stress and quality of life is a growing public health problem that can result in impaired job performance and increased risk of stress-related illnesses, and generates large health care expenditures (Lindert, Müller-Nordhorn, & Soares, 2009). Quality of life of newly diagnosed cancer patients is highly associated with psychosocial factors (Lehto, Ojanen, & Kellokumpu-Lehtinen, 2005). Persons with stress are also having lower quality of life (Colović, Lecić-Tosevsk, Mandić, & Tosković, 2009).

Post-traumatic stress disorder (PTSD) is strongly associated with adverse quality of life (Haagsma et al., 2012) with 59 percent among the PTSD patients having severe impairment in QOL (Rapaport et al., 2005). Symptoms indicative of PTSD were associated with more problems as measured by EuroQol health classification system (EQ-5D) ($p<0.001$) and Health Utilities Index (HUI3) domains on functional outcome showed a considerable utility loss in both hospitalized (0.23 – 0.24) and non-hospitalized (0.32 – 0.33) patients (Haagsma et al., 2012). In patients with PTSD, arousal and endorsement by anxiety or depressive symptoms were the strongest predictors of lower quality of life scores (Doctor, Zoellner, & Feeny, 2011).

Chronic stress has serious health hazards (Koshy, Ramesh, Khan, & Sivaramakrishnan, 2011). A systematic review among multiple sclerosis patients, showed that stress can influence the onset or relapse and clinical course of the disease (Artemiadis, Anagnostouli, & Alexopoulus, 2011). Stress was negatively correlated with speed of wound healing (r=-0.590; $p<0.01$) in healthy adult male thus affecting their quality of life (Ebrecht et al., 2004). Overwork can cause stress that leads to

fatigue related errors that are prone to burnout due to sleep deprivation (Koshy et al., 2011). In animal studies of five colonies of rats exposed to psychological stress, monthly blood pressure measurements using tail-cuff method showed a ten mmHg increase (Henry et al., 1993).

Among the Swedish working population hearing problems were more prevalent among those with symptoms of long-lasting stress. There was a significant difference in the prevalence of hearing problems between those with more symptoms of long-lasting stress compared to those with less for men and women ($p<0.0001$) (Hasson, Theorell, Wallén, Leineweber, & Canlon, 2011). The stress levels among alopecia areata patients were also related to different categories, ranging from physical illness to daily hassles and emotional distress (Matzer, Egger, & Kopera, 2011).

Stress decreases quality of life among parents who have young children with intellectual disabilities (Browne & Bramston, 1998). Patients with stroke had a significant lower quality of life than patients without stroke and a significantly higher level of stress ($p<0.01$). Psychological stress was significantly correlated to all domains of quality of life among non-stroke patients (Baune & Aljeesh, 2006). Among testicular cancer patients who had underwent chemotherapy, 26 percent of the patients and 50 percent of their partners reported clinically elevated levels of stress response symptoms. The patients reported lower physical and social functioning after completion of the chemotherapy compared to one year after chemotherapy (Tuinman et al., 2007).

Stress was observed in 90 percent of the patients with chronic daily headache and nearly half of them was in the phase of almost exhaustion (Galego, Moraes, Cordeiro,

& Tognola, 2007). The majority of the chronic daily headache patients presented with stress and significant reduction in their quality of life. Stress was also related with the development and maintenance of chronic daily headache (Galego et al., 2007).

Stress at work was associated with an almost four-fold increase in risk among men with unexplained chest pain (Fagring et al., 2008). There were 51 percent employees who said they were less productive at work as a result of stress (American Psychological Association, 2009). In a multi-employer, multi-site employee population study, it was found that the healthcare expenditures for employees with high levels of stress were 46 percent higher compared to those employees who did not have high levels of stress (Goetzel et al., 1998). In 2001, the median number of days away from work resulting from anxiety, stress, and related disorders was 25 days higher than the median of 6 days for all non-fatal injury and illness cases (Bureau of Labor Statistics, 2001).

Many measures can be implemented to reduce stress to improve the quality of life in patients living with prostate cancer (Wilkinson et al., 2008). Pre-surgical stress management intervention had significantly higher physical coefficient summary (PCS) scores among prostate cancer patients than men in the standard care group ($p<0.001$) undergoing radical prostatectomy. However, there was no significant group differences of change over time for mental coefficient summary (MCS) score (Parker et al., 2009). Stress management training have shown to bring about improvements in the QOL among myocardial infarction and coronary bypass patients (Trzcieniecka-Green & Steptoe, 1996).

2.3 Health Related Quality of Life (HRQOL)

2.3.1 Introduction

Health-Related Quality of Life (HRQOL) is a multidimensional construct and has many definitions proposed by various authors (Bottomley, 2002)**.** The World Health Organization (WHO) defined quality of life as "the individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectation, standards and concerns" (World Health Organization, 1997). It is a broad-ranging concept incorporating the person's physical health, psychological state, level of independence, social relationship, personal belief and their relationship to salient features of the environment (Luckett, King, & Stockler, 2010; WHOQOL Group, 1994, 1995, 1998; World Health Organization, 1997). HRQOL is a novel variable from the field of public health research that encompasses a wide range of human experience, including necessities of daily living, intrapersonal and interpersonal responses to illness and activities associated with professional fulfillment and personal happiness (Quek & Penson, 2006).

Measuring HRQOL in prostate cancer patients provides helpful information in a variety of clinical circumstances and to investigators in comparing treatments (Quek & Penson, 2006; Talcott & Clark, 1998). For localized and advanced prostate cancer disease, patients are facing a range of therapeutic options associated with troublesome side effects and functional impairment (Herr, 1997). It is a field of public health research that cover a wide range of human experience including intra and interpersonal responses to illness, necessities of daily living and activities that are associated with fulfilment and personal happiness (Lovibond & Lovibond, 1995a).

Over the last decade, the survival and disease-free survival are the critical factors for cancer patients where the overall quality of life is fundamental (Bottomley, 2002). The hypothesis concerning quality of life has been proposed and its implications developed that concluded: (i) the instrument to measure quality of life must cover many aspects of life and life style (Calman, 1984); (ii) the problems and priorities which are important are those of the individual and not of the observer (Calman, 1984; Patrick & Erickson, 1990; Slevin, Plant, Lynch, Drinkwate, & Gregory, 1988); (iii) measurement of quality of life is not sufficient in itself and action should be taken to improve quality of life; (iv) the emphasis should be on the positive aspect of narrowing the gap and improving the quality of life (Calman, 1984); and (v) evaluation of any intervention to modify quality of life is essential (Calman, 1984).

Cancer has a negative impact on HRQOL. The effect of cancer on physical well-being, mental health, social functioning and general health perception have been demonstrated (Boini, Briançon, Guillemin, Galan, & Hercberg, 2004). Men with prostate cancer and clinicians who treat them should be aware of the effects of treatment on quality of life, and weigh them up against the patient's age and the risk of progression of prostate cancer, if untreated to make informed decisions about treatment (Smith et al., 2009). Prostate cancer patients were able to continue and enjoy intimate sexual relationship with full sexual function as well as to continue enjoying other activities (Rothfeld & Romaine, 2005).

2.3.2 Why is HRQOL Important?

There are two main outcome parameters of importance for patients with cancer which are survival and HRQOL. That is why we must have the ability to evaluate survival and HRQOL regularly and thoroughly (Wedding, Pientka, & Ho¨ffken, 2007). HRQOL is a major area of concern in the treatment of cancer patients mostly in elderly patients and those treated within a non-curative approach (Bottomley, V., Flechtner, P., & on behalf of the EORTC Quality of Life Group and the EORTC Data Center, 2003). More clinicians consider the importance of HRQOL as a critical to cancer patients' care (Osoba, 1999). It is perceived to be as important as survival in making treatment decisions (Tanaka & Gotay, 1998).

HRQOL can be used in an individual setting and the clinicians may benefit from completing and using HRQOL data for clinical care-making decision and for treatment. In longitudinal studies of HRQOL, it allows the clinicians and patients to understand the impact of treatment on HRQOL and to make reasonable comparisons of various treatment modalities that can greatly aid in the informed decision making process (Penson et al., 2003a; Penson et al., 2003b). We expect that HRQOL play an even greater role over the coming decade in helping to establish optimal treatment and care approach for cancer patients (Bottomley et al., 2005). Information of HRQOL will improve our knowledge on the effects of diseases, their treatment, on the patient's ability to function and sense of their well-being. (Osoba, 1999).

2.3.3 Measurement of HRQOL in Prostate Cancer Patients

HRQOL is measured using standardized questionnaires which are directly administered to the patients (Quek & Penson, 2005). There are many components in HRQOL such as spirituality and functioning. It is very difficult to observe these components because HRQOL are based on questions organized into scales (Bottomley et al., 2003). Each scale measures a different aspect or domain of HRQOL which are generic (i.e. energy/vitality and performance in physical and social roles) or disease specific (i.e. urinary, sexual, and bowel function) (Namiki & Arai, 2010; Penson et al., 2003b; Quek & Penson, 2005).

Generic instruments focus on the broad aspect of HQROL and health status. They are intended for use in the general population across a wide range of disease conditions (Fayers & Machin, 2007a). The domains address general aspects relevant to all persons regardless of their disease that include overall sense of well-being and self-perceptions and functionality in physical, emotional and social arenas (Quek & Penson, 2005). Meanwhile, disease-specific HRQOL domains focus on the symptoms and are directly relevant to particular conditions or its treatment such as anxiety about cancer recurrence, hot flashes, bladder irritability, bowel dysfunction, sexual dysfunction and urinary incontinence (Quek & Penson, 2005). It may provide detailed information for future management of the patients (Fayers & Machin, 2007a).

Some of the instruments are combined or modified to cover all domains of health important to prostate cancer patients (Herr, 1997). It is very important to focus clearly on specific domains rather than address a more general question (Bottomley et al., 2003). Both generic and disease-specific domains need to be addressed in order to

obtain the most complete “portrait” of the patient’s experience (Quek & Penson, 2006).

Instruments used to assess QOL in prostate cancer include (Namiki & Arai, 2010)**:** (i) global, or generic measures; (ii) cancer-specific measures; and (iii) prostate cancer-specific measures. The domains measured by instruments in one category may overlap with those of another. Table 2.5 shows some of the HRQOL instruments used in prostate cancer.

Table 2.5: The Health Related Quality of Life (HRQOL) instruments used in Prostate Cancer

Instruments:	References
a) Generic measures	
i. SF-36	Ware & Sherbourne (1992)
ii. Nottingham Health Profile	Hunt et al., (1985)
b) Cancer specific measures:	
i. Functional Assessment of Cancer Therapy Scale (General)(FACT-G)	Cella et al., (1993)
ii. The European Organization for Research and Treatment of Cancer QLQ-C30 (EORTC QLQ-C30)	Curran et al., (1997), Fayers et al., (2001), Aaronson et al., (1993)
iii. The European Organization for Research and Treatment of Cancer QLQ-PR25 (EORTC QLQ-PR25)	Andel et al., (2008)
iv. Functional Living Index-Cancer	Schipper et al., (1984)
v. Southwest Oncology Group Quality of Life battery	Carol et al., (1998)
vi. Cancer Rehabilitation Evaluation System	Schag & Heinrich (1990)
vii. Cancer Rehabilitation Evaluation System-Short From	Schag et al., (1991)
c) Disease Specific Measures:	
i. Functional Assessment of Cancer Therapy Scale (Prostate)(FACT-P)	Esper et al., (1997)
ii. UCLA-Prostate Cancer Index (PCI)	Gacci et al., (2005)
iii. Prostate Cancer Specific Quality of life instrument	Stockler et al., (1999)
iv. Prostate Cancer treatment Outcome-Questionnaire	Shrader-Bogen et al., (1997)
v. Expended Prostate Cancer Index Composite (EPIC)	Wei et al., (2000)
vi. 10-Domain Quality of life Instrument	Cleary et al., (1995)
vii. Prostate Cancer-Quality of Life	Geisler et al., (2000)

All HRQOL instruments underwent pilot testing and statistical analyses to ensure the psychometric properties of validity and reliability (Tulsky, 1990). Validity refers to how well the scale or instrument measures the attribute intended to measure which provides evidence to support drawing inferences about HRQOL from the scale scores (Last, 1998). Whereas, reliability is a degree of stability exhibited when a measurement is repeated under identical conditions and the results obtained by a measurement procedure can be replicated (Last, 1998).

The instruments must be responsive (detect changes over time), and sensitive (reflect true changes in individual patients) (Herr, 1997). The contribution of these components to the overall HRQOL depend on the acuteness of disease, current treatment and disease status (Namiki & Arai, 2010). General HRQOL is measured using the RAND 36-item Health Survey or better known as the SF-36 which has been extensively validated in a variety of patient populations and is generally considered to be the "gold standard" for assessing general HRQOL.

2.3.4 Quality of Life in Men with Localized and Advanced Prostate Cancer

There are several issues in prostate cancer in relation to quality of life: (i) the patients may be healthy for years even without treatment, but if they live longer, the disease can be severely disabling or fatal (Herr, 1997); (ii) the therapeutic options for treatments of localized and advanced prostate cancers are similarly successful in providing local and distant control of the cancer and survival (Herr, 1997); (iii) prostate cancer and its treatment commonly affect two areas of major concern to men's physical, mental, and social health, which are urinary and sexual function

(Broome, 2003; Herr, 1997; Penson et al., 2003b); and (iv) prostate cancer produces a tumor marker (PSA) used to track the activity of disease before, during, and after treatment (American Urological Association, 2000; Herr, 1997; Vickers et al., 2009; Vis, 2002).

2.3.4.1 Quality of Life in Men with Localized Prostate Cancer

In early prostate cancer, the assessment of HRQOL is mostly evaluated for the degree of urinary incontinence, sexual impotence after treatment and patients' satisfaction with their outcome (Herr, 1997; Penson et al., 2003b; Quek & Penson, 2005; Smith et al., 2009; Steineck et al., 2002). The clinicians and patients must consider QOL when choosing primary therapy since the patients will be facing the complications in localized prostate cancer such as sexual, urinary and bowel dysfunction (Hoffman et al., 2004).

The Prostate Cancer Outcomes Study (PCOS) investigated a population based cohort of 2693 newly diagnosed patients with localized prostate cancer. It was found that there was no significant difference in the 2-year general HRQOL outcome among the various treatments for localized prostate cancer. However, patients with sexual and urinary dysfunction had significantly worse scores for bodily pain, mental health, role limitation, vitality, and overall health status domains of general HRQOL (Penson et al., 2003b). Another PCOS age-matched case control study of 293 localized prostate cancer patients showed that the cases had better urinary and sexual function than control at baseline. After 5 years, the sexual function declined in control group while the urinary control stayed constant. Both urinary and sexual functions declined in

diseased group and were significantly worse than control. It indicate that the negative effect of localized prostate cancer on urinary and sexual dysfunction is a result of more than just the aging process and is likely a direct result of the various treatments for this condition (Hoffman et al., 2004).

Localised prostate cancer patients had significantly better physical function and less bodily pain but had worse vitality, general health, social function and role limitation compared to healthy controls (Bacon, Giovannucci, Testa, Glass, & Kawachi, 2002). The better HRQOL in the physical function and bodily pain domains was likely due to a result of a "healthy screening" effect because providers are more likely to screen for prostate cancer in younger and healthier patients. However, the observed differences in the other domains, although small, document the fact that localized prostate cancer itself may negatively affect general quality of life (Quek & Penson, 2005).

Castration associated with loss of libido and erectile dysfunction, monotherapy with non-steroidal antiandrogen bicalutamide 150 miligram show the best treatment for hormone therapy in prostate cancer patients for sexual activity (Iversen, Newling, Kirby, & Eardley, 2002). Hispanic men in the US has significant lower quality of life than non-Hispanic White men which was partially mediated by socio-demographic, medical and health behaviour factors (Penedo, Dahn, Shen, Schneiderman, & Antoni, 2006) but patients without pain complaints had significantly better quality of life and habitual well-being and lower anxiety and depression (Gerbershagen et al., 2008).

Active treatment options including various forms of surgery and radiotherapy may be associated with significant adverse effects on urinary symptoms and erectile

dysfunction (Luckett et al., 2010). By including HRQOL in clinical decision-making, we can help our patients make more informed treatment choices for localized prostate cancer (Namiki & Arai, 2010).

2.3.4.2 Quality of Life in Men with Metastatic Prostate Cancer

Metastatic prostate cancer is when the tumour spread (metastasize) to other parts of the body. It is characterized by sclerotic bony metastases and local regional pelvic disease in which changes over time are difficult to assess. The primary tumour sheds cancer cells which travel through the lymphatic system and bloodstream and lodge in other parts of the body usually the bones. Currently, there are no curative treatment for metastatic prostate cancer (Penson et al., 2003b). For these patients, treatment is primarily palliative (Altwein et al., 1997) with the aim on relieving of symptoms such as bone pain (Penson et al., 2003b).

Many studies revealed that symptomatic advanced prostate cancer has a significant impact on quality of life (Penson et al., 2003b). Men with advanced prostate cancer are typically treated using hormone therapy and then chemotherapy and/or radiotherapy to alleviate pain due to bony metastases (Luckett et al., 2010). Being married, having better education and being more affluent tended to slow the rate of decline in the physical domain of HRQOL (Melmed, Kwan, Reid, & Litwin, 2002). The clinician estimates QOL impairment was accurate in more than 60 percent of patients and spiritual well-being (SWB) has a strong relationship with QOL but was not associated with the overall accuracy of clinicians' judgment in advanced cancer patients (Fisch et al., 2003).

Moinpour et al., (1998) found a consistent pattern of better QOL at each assessment during the first six months of treatment for orchidectomized patients with metastatic prostate cancer who received flutamide compared to placebo. Improvement over time was evident in both treatment groups but for patients receiving placebo and patients dying from metastatic prostate cancer appear to experience lower in HRQOL at most domains during their final year of life (Melmed et al., 2002)

2.3.5 The Impact of HRQOL Affecting Treatment Decision

2.3.5.1 The Impact of Radical Prostatectomy on HRQOL

Radical prostatectomy involves surgical removal of the prostate along with nearby tissue. The regional lymph nodes may also be removed to determine whether lymph node metastases are present (American Cancer Society, 2011). It is the most common treatment at the early stage of prostate cancer (Heidenreich et al., 2008; Shah & Sanda, 2002)**.**

It is estimated that only 1 in 100 men with low risk prostate cancer will live longer as a consequence of radical prostatectomy (Sartor & Loriaux, 2006). However, urinary incontinence and erectile dysfunction are the common side effects in the first 2 years after radical prostatectomy (Fowler et al., 1993; Heathcote et al., 1998; Miller et al., 2005; Penson et al., 2003b; Potter & Partin, 1999; Sartor & Loriaux, 2006; Shah & Sanda, 2002; Steineck et al., 2002). Pelvic pain after the procedure is common especially among younger men (Katz & Katz, 2008).

Erectile dysfunction (ED) commonly affects QOL after prostatectomy (Heathcote et al., 1998; Iversen et al., 2002; Miller et al., 2005; Penson et al., 2003b; Potter &

Partin, 1999; Sartor & Loriaux, 2006; Shah & Sanda, 2002; Siston et al., 2003; Smith et al., 2009; Steineck et al., 2002). Erections are typically poor in the first few months after prostatectomy and recovery is variable thereafter depending on the use of nerve sparing, baseline sexual function and patient's age (Iversen et al., 2002; Shah & Sanda, 2002). However erectile functioning may return slowly over the years (Katz & Katz, 2008). The percentage of erectile functioning after surgery was 42 percent (Robinson, Dufour, & Fung, 1997). Loss of sexual function and their effect on QOL need greater emphasis in counseling before radical prostatectomy (Heathcote et al., 1998). Patients who underwent radical prostatectomy show significant increase in functioning in general and in disease specific components during the year after treatment when compared with the scores immediately after treatment (Lubeck et al., 1999).

In a longitudinal study by Litwin et al., (2001) using UCLA-Prostate Cancer Index (UCLA PCI) they found bowel function was the first symptom to return to baseline level (mean 4.8 months); urinary function was intermediate (mean 7.7 months); and sexual function was the last (mean 11.3 months). In a cross sectional study by Wei et al., (2002), it was found that radical prostatectomy was associated with adverse urinary HRQOL. In population study from Prostate Cancer Outcome Study (PCOS), Stanford et al., (2000) found frequent leakage or no urinary control in 8.4 percent of men treated surgically; more than 20 percent of patients reported wearing one or more pads per day up to 24 months after surgery and nearly 60 percent of patients had sexual dysfunction at 24 months postoperatively. Full continence and potency was achieved in 30 percent at 12 months, 42 percent at 24 months, 47 percent at 36 months and 53 percent at 48 months after radical surgery (Saranchuk et al., 2005).

Nerve sparing radical prostatectomy represents an approach of choice in organ-confined disease (Heidenreich et al., 2008; Shah & Sanda, 2002). Those who had nerve sparing had significantly good sexual function compared to those who had no nerve sparing ($p=0.003$) (Toren et al., 2009). The erection can be improved with medication such as sildenafil (Iversen et al., 2002).

After one year procedure for urinary incontinence, 27 percent in 159 patients with bilateral nerve sparing, 17 percent in 32 patients with unilateral nerve sparing and 34 percent in 62 patients with non-sparing patients were having incontinence. However, there was no significant difference between the groups ($p=0.232$) (Toren et al., 2009). Nandipati et al., (2007) found a significant higher incontinence rate in non-nerve sparing group compared to bilateral non nerve sparing after one year procedure ($p<0.05$). However, there was no significant difference in the incontinence rate in unilateral nerve sparing compared to non-nerve sparing group ($p>0.05$) after the same year procedure. There was also an association between age and incontinence where those who are older than 65 years old had more incontinence rate compared to those less than 65 years old (Nandipati et al., 2007).

2.3.5.2 The Impact of Radiotherapy on HRQOL

For early stage of prostate cancer, three types of common radiotherapies are commonly used (Shah & Sanda, 2002). These are: (i) conventional external beam radiation therapy (EBRT), (ii) intensity modulated radiation (IMRT) and (iii) 3-dimensional conformal radiation therapy (3D-CRT). Intensity modulated radiation delivers radiation more precisely to the tumour and is more sparing of surrounding

normal tissue (Shah & Sanda, 2002). Radiation therapy should be performed with at least 72 and 78-Gy in low risk and immediate to high risk prostate cancer (Baker et al., 2008; Heidenreich et al., 2008).

Patients with radiotherapy experience bothersome urinary, sexual and bowel symptoms (Shah & Sanda, 2002). Sexual dysfunction after three years diagnosis was the most common in radiotherapy groups, whereas poor urinary function was less common. (Siston et al., 2003; Smith et al., 2009). Erectile dysfunction was experienced by up to 50 – 60 percent of patients treated with radiotherapy (Iversen et al., 2002). Treatment using 3D-CRT was associated with worsened sexual problem (Miller et al., 2005) and sildenafil is the first-line therapy and was effective in 70 – 80 percent of post radiotherapy patients (Iversen et al., 2002). The probability of maintaining erectile functioning after radiation was 0.69 (Robinson et al., 1997).

Urinary symptoms among radiation patients are characterized by burning or dysuria, urinary frequency, urgency, obstruction and less commonly, haematuria (Shah & Sanda, 2002). Transient irritative and obstructive urinary symptoms occur during and in the period after EBRT (Katz & Katz, 2008; Namiki & Arai, 2010; Shah & Sanda, 2002; Siston et al., 2003). External radiation can lead to bowel symptoms such as frequent, painful and bloody bowel movement or faecal soiling (Katz & Katz, 2008; Potosky et al., 2000). Bowel function was the main complication in those who had external beam radiotherapy (Luckett et al., 2010; Quek & Penson, 2005; Smith et al., 2009). Fatigue appears to be the most common complication in men treated with EBRT from pre-treatment at up to 1 and 12 months follow up (Namiki & Arai, 2010).

2.3.5.3 The Impact of Watchful Waiting on HRQOL

Watchful waiting is an approach to a medical problem in which time is allowed to pass before medical intervention is required (Baker et al., 2008; Heidenreich et al., 2008). Men with watchful waiting should be followed up closely (Dall'Era et al., 2008; Heidenreich et al., 2008) with frequent PSA measurement (every three to four months), digital rectal examination (every three to six months) and imaging (if performed at every nine to 12 months). Repeat prostate needle biopsy should be performed after one year of surveillance and then every 12 to 24 months (Dall'Era et al., 2008)

Men who underwent watchful waiting tended to be older and frailer with more than 50 percent aged between 70 to 79 years (Namiki & Arai, 2010). Urinary obstructive symptoms such as a weak urinary stream were more significantly prevalent among men assigned to watchful waiting (Namiki & Arai, 2010). Poor urinary function was less common (Siston et al., 2003; Smith et al., 2009) and 44 percent men with watchful-waiting compared to 28 percent with prostatectomy reported weak urinary stream. (Steineck et al., 2002).

The prevalence of satisfactory erectile dysfunction is higher in watchful-waiting compared to radical prostatectomy (Steineck et al., 2002). Sexual dysfunction within three years after diagnosis was common in watchful waiting groups (Smith et al., 2009). The patient may improve their quality of life by adopting healthy lifestyles practices mostly on mental and physical HRQOL and sexual function (Daubenmier et al., 2006).

The prevalence of depression, anxiety, well-being and the quality of life in patients with radical prostatectomy and watchful waiting were almost similar. Five percent of moderate or great distress from faecal leakage was reported among watchful-waiting (Steineck et al., 2002). In summary, patients who elect watchful waiting may decline in HRQOL as a result of their prostate cancer (Quek & Penson, 2005).

2.3.5.4 The Impact of Brachytherapy (BT) on HRQOL

Brachytherapy involves placing a small radioactive pellet into the prostate cancer, mostly low dose implants that gradually lose their radioactivity over time. Brachytherapy alone may be recommended for low-risk cancer and combined with electron beam radiation (EBR) (with or without ADT) for intermediate-risk cancer. Brachytherapy is a treatment where radioactive sources are implanted into the prostate gland and the radioactive Pallidum or Iodine seeds are then injected through needles. These low energy radioactive sources had limited tissue penetration allowing for a sharp drop-off at the edge of the gland thus limiting radiation delivery to normal tissue (Shah & Sanda, 2002). BT is recognized as a standard treatment option for men with low-risk prostate cancer (Mettlin, Murphy, McDonald, & Menck, 1999)

Men receiving brachytherapy commonly experience irritative urinary symptoms such as urinary burning, pain, frequency or obstruction (Shah & Sanda, 2002). After brachytherapy, most patients experienced acute urinary symptoms shortly after seed implantation such as urinary retention and urinary incontinence (Heidenreich et al., 2008). The combination of urinary leakage and urinary irritation may explain why patients with brachytherapy reported more urinary problems than surgery or external radiation. Brachytherapy patients reported a significant improvement of HRQOL

compared to controls in urinary-obstructive and bowel domains but worsened urinary incontinence (Miller et al., 2005).

Study by James et al., (2001) found 40 percent of BT patients reported some degree of urinary leakage in their urinary control during the week prior to the procedure (median follow-up: 5.2 years). However, Merrick et al., (2003) reported no differences in long term (median follow up: 64 month) urinary control based on Expended Prostate Cancer Index (EPIC). BT was shown to have long term effects on erection sexually. However, patients on long term follow up after two years post treatment were no better than those who received external radiation. The full effect of seed implants on erections and sexuality develops gradually after treatment and become substantial in one or two years later (Hollenbeck et al., 2002). In bowel function, 11 percent reported bowel habit problems within four weeks after receiving BT (Shah & Sanda, 2002)

2.3.5.5 The Impact of Androgen Deprivation Therapy (ADT) on HRQOL

Androgen deprivation therapy (ADT) is a treatment that can reduce the production or effect of androgen hormones (Baker et al., 2008). It is widely used as systemic treatment for high risk patients treated with radiation therapy for localized prostate cancer. It is effective for palliation in many patients with advanced prostate cancer (Sharifi, Gulley, & Dahut, 2005). Mono-therapeutic ADT is standard care in advanced prostate cancer (Heidenreich et al., 2008).

The adverse effect of ADT include decreased libido, impotence, hot flushes, osteopenia with increased fracture risk, metabolic alterations and changes in

cognition and mood. Localized prostate cancers with high risk disease patients who receive ADT with radiation have survival benefit. It is clear that ADT has a clear quality of life benefit but no benefit among advanced prostate cancer (Sharifi et al., 2005)

2.3.5.6 The Impact of Cryosurgery on HRQOL

Cryosurgery is an operation using very low temperatures (below -190 degree Celsius). The destruction of the cancer tissue occurs at extremely cold temperatures. The technique of exposing tissue to extremely cold temperature is to produce well demarcated area of cell injury and destruction of the cancer cell (Rees, Patel, MacDonagh, & Persad, 2004**).** The introduction to gas-based third generation cryosurgery decreased the complications such as incontinence, urethral and recto-urethral fistula (Langenhuijsen, Broers, & Vergunst, 2009**).** This technique is increasingly preferred for the treatment of localized prostate cancer patients who experienced a recurrence episode after radiation therapy (Namiki & Arai, 2010).

However, there are few studies investigating the HRQOL issues related to this treatment (Namiki & Arai, 2010**).** Three years after the procedure of cryosurgery, 13 percent had regained erectile function and 34 percent were able to have intercourse with the help of erectile aids (Robinson et al., 2006).

2.3.5.7 The Impact of Orchidectomy (Androgen withdrawal) on HRQOL

Orchidectomy is removal of one or both testicles in males (Baker et al., 2008). It has a rapid effect on testosterone level and is used as an alternative to continuous LHRHs

therapy (Viau & Meaney, 1996). Patients who receive orchidectomy plus placebo had better quality of life scores compared to patients receiving orchidectomy plus flutamide. The mental health index (MHI) of patients receiving flutamide was reported to be significantly lower than patients receiving placebo at two of three follow up assessment (both $p<0.003$) (Moinpour et al., 1998).

2.3.5.8 The Impact of Hormonal therapy on HRQOL

Luteinising hormone-releasing hormone (LHRH) agonist has become a standard care in hormonal therapy (Heidenreich et al., 2008). Hormone therapy is associated with problematic side effects such as hot flushes and gynaecomastia in nearly 20 percent of patients. The indication of hormonal therapy is to palliate symptoms and to reduce the risk for potentially catastrophic sequelae of advanced disease like spinal cord compression, pathological fracture, urethral obstruction and extra skeletal metastases (Heidenreich et al., 2008).

Study by Siston et al., (2003) found that men with metastatic prostate cancer undergoing hormonal therapy, had a significant decrement in role, social and sexual functions at three months but resolved on average by 12 months of follow up. Many clinical trials established the role of hormonal therapy as an effective adjuvant to either external radiation or surgery in cases with advanced risk of prostate cancer (Messing et al., 1999). Hormonal therapy had significant improvements in prostate cancer patient who reported on health change during a year after treatment (Lubeck et al., 1999). Other symptoms include loss of vitality or energy, weight gain and fatigue.

Impotence during hormonal therapy is common and recovery or erection after stopping hormonal therapy is variable (Shah & Sanda, 2002).

The andropause syndrome is very common in men undergoing hormonal ablation therapy for prostate cancer. The most common side effects among prostate cancer patients are hot flashes, anemia, gynecomastia, depression, cognitive decline, sarcopenia, a decreased overall quality of life, sexual dysfunction and osteoporosis with subsequent bone fractures (Thompson, Shanafelt, & Loprinzi, 2003).

2.4 Relaxation

2.4.1 Introduction

The Merriam Webster's Collegiate Dictionary defines relaxation as "the act of relaxing or state of being relaxed, a relaxing or re-creative state, activity or pastime and the lengthening that characterizes inactive muscle fibres or muscle" (Mish, 2008). Beck (1984) described relaxation as doing nothing. However, in a more comprehensive view of relaxation, it is quoted as a "state of consciousness characterized by feelings of peace, and release from tension, anxiety and fear" (Rayman, 1995) and "a state of or the action resulting in diminution of muscular tension" (Becker, 1989).

2.4.2 Relaxation Technique

Relaxation techniques are commonly used in physical and manual therapies (Payne, 2000). The primary goal is elicitation of a psycho-physiological state of relaxation or arousal and thereby alleviate or prevent stress-related symptoms (Fink, 2000) with the aims of achieving a hypo-metabolic state of reduce sympathetic arousal (Astin, Shapiro, Eisenberg, & Forys, 2003). It has become one of the central interventions of behavioural medicine.

There are various relaxation techniques used to produce changes in autonomic and skeletal responses in the direction of parasympathetic control and reduced muscle tension (Philips, 1991). Relaxation techniques include behavioural therapeutic approaches that differ in philosophy, methodology and practice but most of them are sharing certain related features and share the components of repetitive focus adoption

of a passive attitude towards intruding thoughts and return to the focus (Payne, 2000). Relaxation skills provides a safe, pleasurable and cost effective preventive measure and it gives a wide variety of efficacious techniques which are suitable to the individual's life style (Fink, 2000). Females have been found to practice relaxation therapy more compared to men (OR=4.38, 95%CI: 1.25 – 15.29) and adolescents with more severe disease are willing to use relaxation in the future (OR=4.17, 95%CI: 1.07 – 16.29) as compared with patients with less severe disease (Cotton et al., 2010). Relaxation programmes help to relax muscle and thus reduce spasm (Sims & Olson, 2002) and relaxation training influences the immune system in a positive way (Rohrmann, Henning, & Netter, 2000).

2.4.3 Relaxation Response

Relaxation response is a physical state of deep rest that change the physical and emotional response to stress (Benson, 1975). The relaxation response is believed to be an integrated hypothalamic response that results in generalized decreased sympathetic nervous system activity and this response consists of changes opposite to the "fight-or-flight reaction" (Benson, 1975; Buckingham, Gillies, & Cowel, 1997).

The main physiological elements of the relaxation response were to decrease oxygen consumption, carbon dioxide elimination and changes in heart rate, respiratory rate, ventilations and arterial blood lactate (Pokharna, 2003). The systolic, diastolic, and mean blood pressures and rectal temperatures remain unchanged whereas skin resistance increased and skeletal muscle blood flow is slightly increased. The changes are consistent with generalized decreased sympathetic nervous system activity and are

distinctly different from physiological changes noted during quiet sitting or sleep (Davidson & Schwartz, 1976; Pokharna, 2003).

2.4.4 Classification of Relaxation Techniques

Lichstein (1988) classified relaxation technique into deep relaxation and brief relaxation. Deep relaxation refers to procedures that focus on both the mind and the body. It is carried out in a calm environment e.g. progressive relaxation, autogenic training and meditation. It also refers to the full process of total body relaxation. Some approaches to deep muscle relaxation involve tensing the tight muscles or muscle group and then letting go the tension and is always practiced along with deep breathing (Payne, 2000). Meanwhile, brief relaxation refers to techniques which produce immediate effects and can be used when the individual is faced with stressful events and can be applied in everyday life. For this relaxation, it is best to be seated with eyes closed, feet flat on the floor or cross at the ankles and hands resting comfortably on the lap (Payne, 2000). The exercise begins by taking a deep breath and then gently exhaling. After doing each exercise slowly, it is gently activated by a little deeper and exhaling breathing (Sultanoff B & Zalaquett C, 2000).

Deep and brief relaxations fall roughly into one of the three broad categories (Payne, 2000): (i) somatic method including Jacobson's Progressive Relaxation (Jacobson, 1938), Bernstein & Borkovec's Medified Version, Everly & Rosenfeld's Passive Relaxation, Madders' Release-only, Ost's Applied Relaxation, Poppen's Behavioural Relaxation Training, The Mitchell Method, The Alexander Technique (Pryer, 2002), Differential Relaxation, Stretching, Exercise and Breathing Methods; (ii) Cognitive

method includes Self-awareness, Imagery (Kemp, 1995), Goal-directed Visualization, Autogenic Training (Fink, 2000; Gonzales, 1997), Meditation, Benson's Relaxation Response and Cognitive Behavioural Approaches; and (iii) other techniques e.g. massage (Field, Diego, & Hernandez-Reif, 2007)**,** aromatherapy, biofeedback assisted relaxation therapy (Fink, 2000; Pryer, 2002; Reber & Reber, 2001), body awareness therapy, Feldenkrais relaxation, functional relaxation, yoga, eastern techniques, reflex therapy, shiatsu, t'ai chi ch'uan, smiling and laughter therapy.

2.4.5 Aims of Relaxation Therapy

Relaxation is one modality that can be taught as a form of self-help that can achieve a state of mental calmness (King & Remanyi, 1989). Basically it has three aims in situations where stress plays a major role (Titlebaum, 1988):

i. as a preventive measure for the organs involved in stress-related disease to protect organs from unnecessary wear (Payne, 2000).
ii. as a treatment to relieve stress related disorder that may help to make the body's innate healing mechanism more available such as essential hypertension (Nickel et al., 2005; Patel & Marmot, 1988; Salt & Kerr, 1997), tension headache (Kanji, White, & Ernst, 2006), asthma (Erskine & Schonell, 1979; Holloway & West, 2007; Huntley, White, & Ernst, 2002), panic disorder (Austin, Blashki, Barton, & Klein, 2005; Goisman, Warshaw, & Keller, 1999; Ost & Westling, 1995) and many others; and
iii. as a coping skill to calm the mind and allow thinking to become clearer and effective. Relaxation can help to resolve clarity of thought and it has been

found that positive information in memory becomes more accessible when a person is relaxed (Peveler & Johnston, 1986).

Most of relaxation techniques need to be practiced daily to be effective. Some techniques are easy to learn but some techniques take years to master (Vickers, Zollman, & Payne, 1999)

2.4.6 The Benefits of Relaxation Therapy

Relaxation therapies have potential benefits and advantages. The relaxation technique do affect some clinical symptoms with the effect size analyses ranging from 0.43 to 0.66 (Hyman et al., 1989)**.** The effectiveness of the various relaxation techniques depend on the acquisition of particular skills and thus is typically improved by formal instruction and regular practice. The most significant benefits of relaxation techniques usually accrue when practice becomes part of a daily routine (Fink, 2000).

In rehabilitation, the progressive muscle relaxation (PMR) therapy is a well-established psychological therapy for many symptoms and diseases. Relaxation can decrease the body's oxygen exchange, lower metabolism, decrease both respiratory and heart rates, decrease muscle tension, decrease systolic and diastolic blood pressure, increase alpha brain waves and enhance immune function (Tiran & Mack, 2000). Relaxation therapy has positive effect on psychological functioning like depression (Leo´n-Pizarro et al., 2007; Yu, Lee, & Woo, 2007), anxiety (Brenes, 2003; Cheung, Molassiotis, & Chang, 2003; Cole & Tufano, 2008; Dehdari, Heidarnia, Ramezankhani, Sadeghian, & Ghofranipour, 2009; Goisman et al., 1999; Leo´n-Pizarro et al., 2007; Navaneethan & Soundara Rajan, 2010; Ozdemir &

Pasinlioglu, 2009; Yu et al., 2007) and stress (Bastani, Hidarnia, Kazemnejad, Vafaei, & Kashanian, 2005; Cole & Tufano, 2008; Smith, Hancock, Mortimer, & Eckert, 2007). Relaxation is also associated with improvement in health related quality of life (Cheung et al., 2003; Dehdari et al., 2009; Leo´n-Pizarro et al., 2007; Smith et al., 2007). It is particularly helpful for patients coping with chronic illness and in need of palliative care.

Progressive muscle relaxation has been applied to the treatment for other than depression, anxiety, stress and quality of life. It seems to be useful as an adjunctive non-pharmacologic treatment modality in the management of heart failure (Yu et al., 2007) and bronchial asthma (Nickel et al., 2005). In the therapy for hypertension, most studies showed a small and significant reduction in systolic and diastolic blood pressure. However, some only show transient effects while applying relaxation therapy (Frankel, Patel, Horwitz, Friedewald, & Gaarder, 1978; Nickel et al., 2005; Perez-Stable, 1987; Ranjbar F, Akbarzadeh F, Kazemi B, & Safaeiyan A, 2007). In repeated relaxation training, it can increase secretory immunoglobulin A level, particularly in subjects high in anxiety and this may be effective for the treatment of diseases associated with low secretory immunoglobulin A levels (Rohrmann et al., 2000).

A systematic review by Carrol & Seers (1998) found the pain scores assessed by McGill Pain Questionnaires were significantly lower for patients receiving relaxation compared to those who were in the routine treatment control group. Among osteoarthritis patients, the combination of guided imagery with progressive muscle relaxation can reduce chronic pain and mobility (Baird & Sands, 2004).

2.4.7 Progressive Muscle Relaxation (PMR)

Progressive muscle relaxation (PMR) is one of the famous systematic techniques to create a state of deep relaxation (Payne, 2000). It has been developed by Edmund Jacobson in 1930. It involves flexing specific muscles, holding that position, and then relaxing the muscle (Jacobson, 1938, 1970; Sadock & Sadock, 2003; Wolpe & Lazarus, 1966). PMR is originated from the theory of psychobiological state called neuromuscular hypertension. It is the basis for a variety of negative emotional states and psychosomatic disease (Jacobson, 1938) and is based on the theory that the body's muscle tension results from anxiety-provoking thoughts and events (Nickel et al., 2005)**.**

This technique creates a state of deep relaxation and often involves progressing through the muscle groups of the body one at a time and can be practiced while lying down or sitting (Pryer, 2002). It will required spending approximately one hour of training on each of approximate 44 muscle groups (Jacobson, 1938). Davidson and Schwartz (1976) suggest three effects of relaxation which are; (i) somatic response that effects on physiological parameter (eg. normalizing blood supply to the muscles; decreasing oxygen consumption, heart rate, respiration and skeletal muscle activity); (ii) cognitive effects that pertain to mental activity; and (iii) attentional effect that relates to continuum represented by active, self-regulating behavior (eg. controlling breathing) and at the other pole, as passive awareness of a pre-existing behavior without any overt attempt to modify. The multi-process theory incorporates a "specific-effects" hypothesis which suggested that relaxation techniques have

different effects depending on the relative and somatic components involved in that technique.

Edmund Jacobson demonstrated relaxing of mind and the body and entails physical and mental components (Jacobson, 1970). The physical component involves tensing and relaxing of muscle groups over the legs, abdomen, chest, arms and face. The mental component focuses on the difference between the feelings of the tension and relaxation (Sadock & Sadock, 2003). The tensed muscle relates to both physiological activities and cognitive states and the relaxing musculature can lead to mental and sympathetic activity (Jacobson, 1938). The longer tension intervals may contribute to greatest relaxation effect (O'Bannon, Rickard, & Runcie, 1987). The PMR is purported to decrease the arousal of the autonomic and central nervous system and to increase parasympathetic activity (Cooke, 2012).

2.4.8 Abbreviated Methods of Progressive Muscle Relaxation

The classical progressive muscle relaxation was time-consuming that required 44 individual sessions. Since then, many abbreviated methods of progressive muscle relaxation have been developed. The modified technique tends to be shorter, rely on the tape-recorded instruction and tend to use hypnotic-like suggestions in order to induce relaxation. Its involves a feeling of 'contrast' between large contractions of many muscle groups at once and subsequent release (Lehrer, 1982). In 1948, Joseph Wolpe adapted the progressive muscle relaxation for use with systematic desensitization and in 1973, Bernstein and Borkovec studied adjustments to a

technique to fit on cognitive behavioural stress management (McCallie, Blum, & Hood, 2006).

Progressive muscle relaxation training (PMRT) is a short version of Jacobson's (1938) original progressive muscle relaxation technique. It involves tensing and relaxing 16 different muscle groups; it is a brief relaxation exercise compared to the classical one which involved more than 40 different muscle groups. These methods fall into two types: (i) those consisting of training the voluntary contraction and relaxation of skeletal muscle groups; and (ii) those utilizing auto-suggestive or overtly hypnotic procedures intended to influence autonomic function (Mathews & Gelder, 1969). PMRT can enhance immune function (Pawlow & Jones, 2002). However, the original Jacobson's technique is more powerful than the modified techniques in reducing activation and various symptoms of stress (Lehrer, 1982). The difference between Jacobson's progressive relaxation method and Progressive Relaxation Training is shown in Table 2.6 (Payne, 2000).

Table 2.6: The difference between Jacobson's progressive relaxation method and Progressive Relaxation Training

	Progressive Muscle Relaxation	**Progressive Muscle Relaxation Training**
Position of relaxation	Lying or sitting	Reclining
Total number of muscle group worked	40+	16
Number of new muscle groups worked in one session	1 or 2	All groups
Emphasis of technique	Releasing tension	Producing relaxation through tense-release cycles
Perceived value of the contraction	To alert the individual to the tension sensation	To deepen each relaxation component by providing a 'running start'; a strong contraction leads to a deep relaxation
Part played by suggestion	None: the technique is purely a muscular skill	Indirect suggestion is used to enhance the effect
Use of tapes	Not used	Advised against
Number of sessions needed	50+	8-12

Adapted from Rosemary A. Payne (2000)

There are many different forms of relaxation training such as "applied relaxation", which consists of breathing techniques and muscle relaxation. Breathing is an automatic process governed by the center in the brain stem (pons and medulla). It is directly linked to the system that controls physiological arousal that adds to its potential to induce physiological relaxation (Lichstein, 1988). In this research, the applied progressive muscle relaxation training was applied to the intervention groups

since the relaxation therapy consists of breathing techniques and modified progressive muscle relaxation.

2.4.9 The Mechanism of Relaxation

There are two theories that are responsible to bring about the state of relaxation: (i) the physiological aspect such as autonomic activity and muscle tension and (ii) psychological aspect such as attitude towards the self.

2.4.9.1 Physiological Theories

There are three systems that are involved in the physiology of the relaxation mechanism which are: (i) the autonomic nervous system; (ii) the endocrine system; and (iii) the skeletal musculature.

2.4.9.1.1 The Autonomic Nervous System (ANS)

The physiological arousal in the body is governed by the autonomic nervous system. It has two branches (Widmaier, Raff, & Strang, 2006): (i) the sympathetic branch that increase arousal when the organ is under threat; and (ii) the parasympathetic branch that restores the body to the resting state. During normal functioning of the autonomic nervous system, the parasympathetic branch is controlling the body (Figure 2.7).

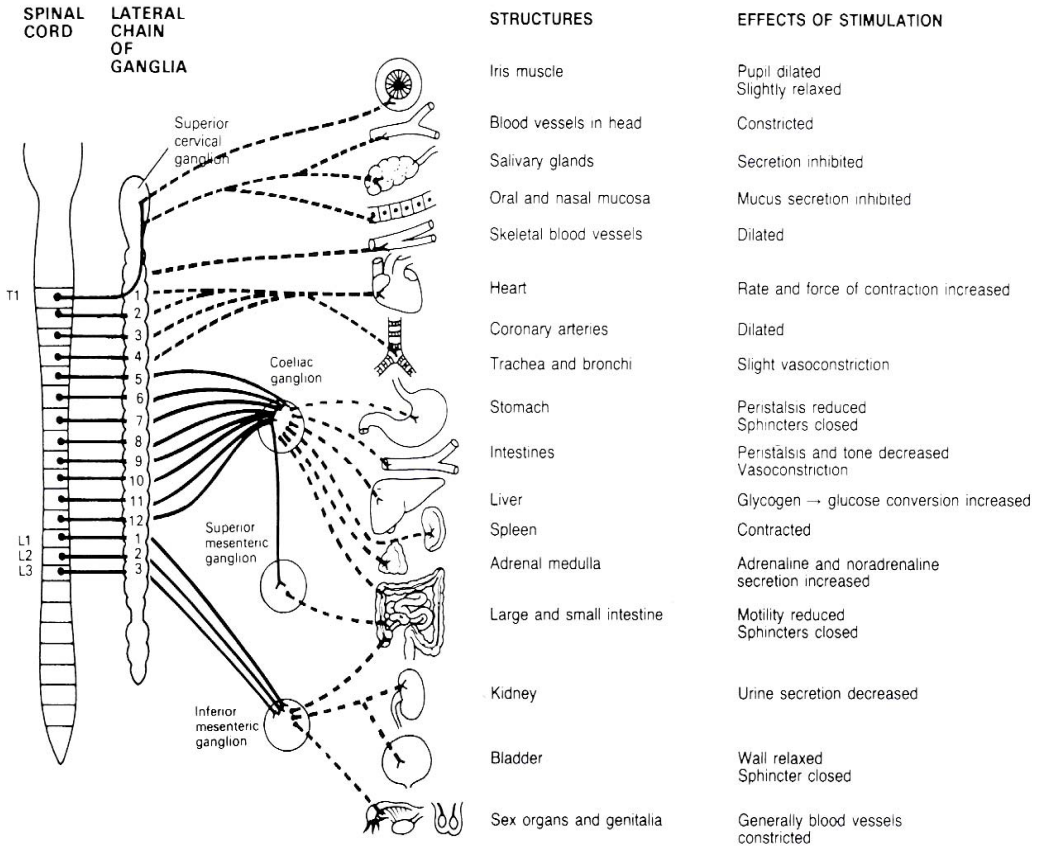


Figure 2.7: The Sympathetic Outflow. The main structures supplied and the effects of stimulation. Solid lines pre-ganglionic fibers; broken lines postganglionic (Payne, 2000)

However, in a situation of challenge, excitement or danger, the sympathetic nervous system becomes aroused to aid in the body's ability to cope with the difficulties by increasing the activity of the heart and redistributes blood from the visceral to the involuntary muscle (Figure 2.8).

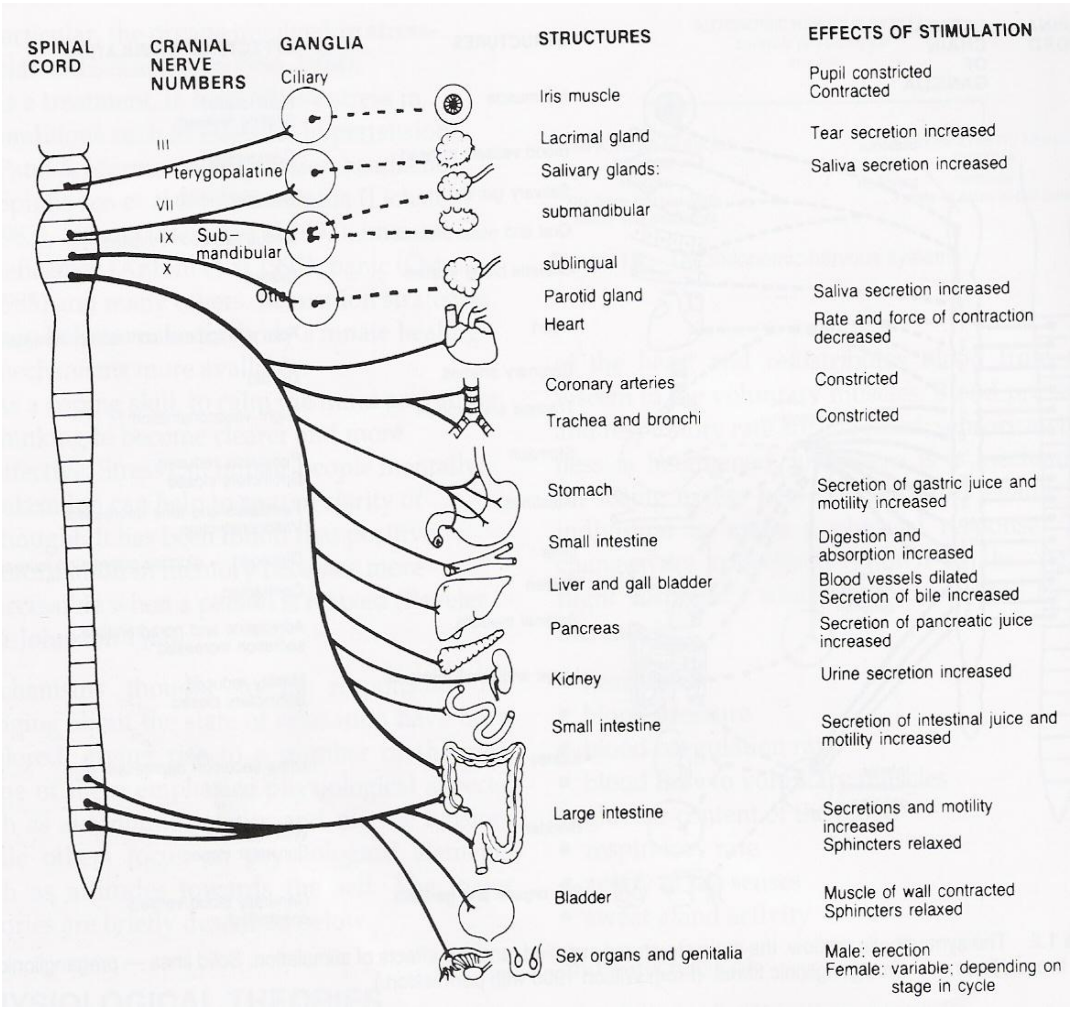


Figure 2.8: The Parasympathetic Outflow, the main structures supplied and the effects of stimulation. Solid lines pre-ganglionic fibers; broken lines, postganglionic fibers (Payne, 2000).

During this time, the parasympathetic nervous system relinquishes control of the body, so that the body is able to respond physically to protect itself. This action is referred as the "fight-flight response" or a "critical response" (Beck, 1984; Neimark, 2000). The "fight-flight response" was characterized by Neimark (2000) and Widmaier et al., (2006) which are: (i) an increase in heart rate, blood pressure, blood coagulation rate, blood flow to voluntary muscle, glucose content of the blood, respiratory rate, the activity of the sensory and sweat glands; and (ii) decreased

activity in the digestive tract. In the absence of challenge or excitement, the activities are reversed (Neimark, 2000).

The relaxation response counteracts the effect of sympathetic activity by promoting the action of the parasympathetic, thereby exploiting the reciprocal nature of the two parts of the autonomic nervous system. Once the threat is over, the parasympathetic nervous system restores the body to its preceding calm state. A reduction of sympathetic activity would lead to increased secretory Immunoglobulin A production (Rohrmann et al., 2000).

2.4.9.1.2 Endocrine System

The adrenal glands and the endocrine system are closely associated with the autonomic nervous system. The adrenal glands are situated above the kidneys and consist of medulla and cortex. The function of adrenal glands is to produce hormones that modify the action of the internal organ in response to environmental stimuli (Widmaier et al., 2006). When a situation is perceived to be stressful, the brain immediately responds by stimulating the adrenal medulla to release the catecholamines (adrenaline and noradrenaline). The function of these neurotransmitters is to prepare the organ for action by increasing alertness and redistribution of blood. Acting in the longer term, the pituitary gland releases the adrenocorticothropic hormone (ACTH) that stimulates the adrenal cortex to produce mineralocorticoid and glucocorticoid. The glucocorticoid releases mostly cortisol that helps to maintain the fuel supply to the muscle (Buckingham et al., 1997).

The stimulation of normal levels of cortisol enhances the immune system (Jefferies, 1991) and high level of cortisol, such as those created by prolonged stress associated with a suppressed immune system. Under these challenges, the entire cortisol is reduced. When the situation of challenges passes, the neurotransmitter acetylcholine is released to restore a state of balance in the autonomic nervous system. It was found that the progressive muscle relaxation can cause significant lower level of salivary cortisol and it also enhances immune function (Pawlow & Jones, 2002).

2.4.9.1.3 Skeletal Musculature

The tension-release in the skeletal musculature has an effect on calming the mind (Jacobson, 1938). The progressive muscle relaxation consists of tense-release technique designed to cultivate awareness of muscular sensations and this awareness allows the individual to develop the skill of consciously releasing tension. It involves sequential tensing and relaxation of major skeletal muscle groups with the aim of inducing relaxation (Cooke, 2012)

2.4.9.2 Psychological theories

The psychological theories concerning relaxation can be divided into three which are: (i) cognitive, (ii) behavior and (iii) cognitive-behaviour.

2.4.9.2.1 Cognitive Theory

Cognitive theory is a learning theory that attempts to explain human behavior by understanding the thought processes (Fritscher, 2011). Cognitive structures are

beliefs, values and commitments that underlie thoughts, speech and action (Pokharna, 2003). It states that our thoughts rule our feelings and they also rule our lives. For example, '*I'm going to have a heart attack*'. It is a cognitive aspect in anxiety by negative thoughts.

The cognitive view resembles psychodynamic explanations of behaviour in that irrational thoughts are seen to be interfering with healthy life (Maire, 2003). The interpretation, perceptions, assumptions and conclusion will give rise to a particular feeling that governs our behaviour (Payne, 2000). Cognitive theory has led to conceptual models for many disorders including anxiety, addictions, bipolar, eating, personality and psychotic disorder (Kazantzis, 2006)

2.4.9.2.2 Behavioural Theory

Behavioural theory views human behaviour as a result of environmental conditioning (Payne, 2000). It attempts to explain how people learn and act, for example by tense postures and different kinds of un-relaxed activities. When the behaviour is maladaptive, it employs methods such as reinforcement, distraction and exposure to modify it. Positive reinforcement is a method for increasing the likelihood of a certain behaviour and negative reinforcement refers to the withdrawal of certain actions in order to extinguish a behaviour (Schoenfeld, 1995). Distraction is holding the attention elsewhere and exposure is useful as a tool for helping people who experience panic attack or various forms of social anxiety. Behavioural theories never explain the cause of mental disorder, but focus on normal human behaviour.

2.4.9.2.3 Cognitive-Behaviour Theory (CBT)

Cognitive behavioural theory (CBT) is the study of human psychology that deals with the various facets of human personality and behaviour (Karthik, 2012). Cognitive-behavioural theory is based on the premise that psychological disorder is determined by the meanings that individuals make of events, rather than the event themselves (Kazantzis, 2006). The concept of cognitive-behavioural theory is the different relaxation techniques that require different levels of relaxation skill. Relaxation skills primarily refer to a participants' ability to focus (i.e. identify, differentiate, maintain attention on and return attention to simple stimuli for an extended period) (Smith, 1990).

Cognitive-behavioural theory combines both cognitive and behaviour theories that helps in thinking processes, such as attitudes and belief, unwanted thoughts and behavioural therapy that focuses on behaviour in response to those thoughts. It sees thoughts processes as learned and maintained through reinforcement (Maire, 2003). According to Aaron (1984), he believed that dysfunctional behaviour is caused by dysfunctional thinking and that thinking is shaped by our beliefs and our beliefs decide the course of our action.

2.4.10 Review of Clinical Studies of Progressive Muscle Relaxation (PMR) on Depression, Anxiety, Stress and Health Related Quality of Life (HRQOL)

There are many progressive muscle relaxations (PMR) studies conducted targeting in the reduction of depression, anxiety and stress levels and increasing quality of life. Table 2.7 shows the clinical research of the PMR targeting on quality of life,

depression, anxiety and stress in certain groups of people and patients and their impact.

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
Smith et al., (2007)	Comparative trial Yoga and relaxation for 1 hour per week for 10 weekly	RCT: • State-Trait Personal Inventory sub-scale Anxiety (STPI) • General Health Questionnaire (GHQ-12) • SF-36 Participants (mild to moderate stress): • 131 randomized; • At the end : i. 65 yoga ii. 53 relaxation	To compare yoga and relaxation treatment modalities at 10 and 16 weeks either can reduce stress, anxiety, blood pressure or improve quality of life in the community in Australia	**Changes in effects between yoga and relaxation groups** Yoga vs relaxation: Short term baseline to 10 weeks (Mean diff, p-value); Long term effects 10 – 16 weeks (Mean diff, p-value) **STPI**: -0.89, 0.45, 0.34, 0.74 **GHQ**: 0.84, 0.54, 1.35, 0.23 **SF-36:** - PF: 0.34, 0.90, -0.09, 0.68 - PR: 2.67, 0.76, -1.47, 0.82 - GH: -0.61, 0.76, 0.05, 0.97 - RE: -8.26, 0.33, -3.38, 0.63 - SF: 3.54, 0.46, -8.42, 0.02* - BP: -1.21, 0.74, -1.46, 0.69 - MH: 7.80, 0.02*, -7.05, 0.01* - VT: 5.28, 0.11, -7.06, 0.04* **STPI:** • No significant differences at short term effect (mean diff: -0.89 (95%CI: -3.25, 1.40), p=0.45] and long term [mean diff: 0.34 (95%CI: -1.69, 2.37), p=0.76]. **GHQ:** • No significant differences at short term effect (mean diff: 0.84 (95%CI: -3.58, 1.89), p=0.54] and long term [mean diff: 1.35 (95%CI: -0.89, 3.60), p=0.23].	• Stress, anxiety and QOL scores improved over time. • Yoga provides better improvement in stress, anxiety and health status (seven domains in SF-36) compared to relaxation therapy. • Yoga was more effective than relaxation in improving mental health • At 6 weeks follow up: no differences between group in stress, anxiety and 5 domains in SF-36 • Vitality, social function and mental health were higher in relaxation group

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
				SF-36: • Yoga was found to be effective as relaxation in reducing stress and anxiety and improve 7 domains of QOL • Yoga was more effective than relaxation in improving mental health at short term effect [mean diff: 7.80 (95%CI: 1.06, 14.55), p=0.02]. • At long term effect: there were a significant differences in social functioning [mean diff: -8.42 (95%CI: -15.70, -1.12), p=0.02], mental health [mean diff: -7.05 (95%CI: -12.63, -1.47), p=0.01] and Vitality [mean diff: -7.06 (95%CI: -13.97, 0.15), p=0.04]	• Yoga appears to provide a comparable improvement in stress, anxiety and health status compared to relaxation
Chen et al., (2009)	PMR Training • Eleven- 45 minutes over 11 consecutive days (posttest) and one week after the finalization of intervention (follow up).	RCT (Blocked randomization) using repeated measures. Randomly assign Instrument: • Beck Anxiety Inventory (BAI) Participants: • 18 randomized (9 intervention + 9 controls)	To determine the efficacy of progressive muscle relaxation training on anxiety in schizophrenia patients	**BAI:** GEE analysis examine the changes between intervention and control: **Intervention** / **Control** Prior intervention: 16.4 (4.4) / 15 (3.9) Baseline: 16 / 15 1-week post intervention: 7 / 13	• PMR training effectively alleviate anxiety in schizophrenia patients

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

<table>
<tr><th>Authors</th><th>Type of treatment & duration</th><th>Study
Design & program
Participants</th><th>Treatment</th><th>Results</th><th>Conclusion</th></tr>
<tr><td>Emery et al., (2008)</td><td>Progressive muscle relaxation training (PMRT) 25-minute
• Pre-test before intervention, on day 11 and one week post-test after the intervention</td><td>RCT:
Randomly assigned

• Visual Analogue Scale Stress (VASS)

Participants:
• PMRT: 28
• Control: 27 (male, n=26) and women, n=29)

• At the end :
i. 8 intervention
ii. 6 controls</td><td>Effect on nociceptive flexion reflex (NFR) threshold in healthy young adults</td><td>VASS:
<table><tr><th>VASS</th><th colspan="2">PMR (n=28)</th><th colspan="2">No PMR (n=27)</th></tr><tr><td></td><td>Time 1</td><td>Time 2</td><td>Time 1</td><td>Time 2</td></tr><tr><td>Stress</td><td>39.8 (26.3)</td><td>22.7 (21.8)</td><td>31.5 (24.7)</td><td>24.7 (22.9)</td></tr></table>VASS reduced significantly in the PMRT group (mean diff: 17.1, p<0.001) and in control group (mean diff: 6.8, p<0.05)
<table><tr><th>Interaction:</th><th>Estimate (95%CI)</th><th>z-value</th><th>p-value</th></tr><tr><td>Group x after post test</td><td>-12.6 (-18.7, -6.5)</td><td>-4.1</td><td><0.001</td></tr><tr><td>Group x follow up</td><td>-7.8 (-15.5, -0.2)</td><td>-2.0</td><td>0.0046</td></tr></table></td><td>PMR has an efficacy in reducing nociceptive response and behavioural pain management strategies</td></tr>
<tr><td>Lahmann, et al., (2008a)</td><td>Functional Relaxation (FR) + short patient Education (PE):
• 10 sessions of FR supplemented by the 60-minute of PE</td><td>RCT:
Randomized in a 1:1 ratio

Instrument:
• Somatization and Anxiety of the symptom Checklist of Derogatis (SCL-90)</td><td>Somatoform heart disorder patients (nonspecific chest-pain)</td><td>SCL-90:
<table><tr><th>Variables</th><th>Difference between two groups in reduction in score</th><th>p-value</th></tr><tr><td>Depression</td><td>3.0 (0.0 – 7.0)</td><td>0.073</td></tr><tr><td>Anxiety</td><td>7.0 (3.0 – 11.0)</td><td>0.001*</td></tr><tr><td>Phobic Anxiety</td><td>5.0 (-1.0 – 8.0)</td><td>0.480</td></tr></table>The Somatization and Anxiety subscales of SCL-90 showed distinctly increased scores, whereas the remaining subscales were within normal range in both group</td><td>• Functional relaxation (FR) is effective in improvement on all primary end-point and the GSI subscale of the SCL-90 than treatment within enhanced medical care.
•</td></tr>
</table>

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

<table>
<tr><th>Authors</th><th>Type of treatment & duration</th><th>Study
Design & program
Participants</th><th>Treatment</th><th>Results</th><th>Conclusion</th></tr>
<tr><td></td><td></td><td>• Giessen Inventory of Complaints (GBB)

Participants:
• FR + PE: 11
• Control: 11</td><td></td><td></td><td>• FR is to be safe and effective approach in treating somatoform autonomic dysfunction of the heart and DVS system</td></tr>
<tr><td>Lahmann et al., (2008b)</td><td>• Brief relaxation (BR) (functional relaxation) vs music distraction (MD) in comparison with control (no intervention)
• BR in a 10-minutes training session
• Then the post assessment immediately after completion the dental treatment.</td><td>RCT
• Concealed allocation by using randomized number generated by electronic spreadsheet

Instruments:
• STAI
• Hierarchical Anxiety Questionnaire (HAQ)

Participants
• BR = 29
• MD = 28
• Control (C) = 30
:</td><td>Dental anxiety – simple caries patients</td><td>STAI-S:
<table><tr><th></th><th>Initial score</th><th>Final score</th><th>Mean score diff</th></tr><tr><td>• BR (n=29)</td><td>42.4 (10.4)</td><td>29.4 (6.3)</td><td>12.0 (9.5)</td></tr><tr><td>• MD (n=28)</td><td>41.3 (9.6)</td><td>36.8 (9.8)</td><td>4.4 (4.6)</td></tr><tr><td>• C (n=30)</td><td>41.9 (11.5)</td><td>40.5 (11.2)</td><td>1.4 (4.4)</td></tr></table>Difference in before and after
<table><tr><th>Group</th><th>p-value</th></tr><tr><td>• BR vs C</td><td>p<0.001</td></tr><tr><td>• MD vs C</td><td>p<0.028</td></tr><tr><td>• BR vs MD</td><td>p<0.001</td></tr></table>Effect of intervention in relationship to anxiety level before dental treatment
<table><tr><th rowspan="2">Anxiety level</th><th colspan="3">Mean diff. before and after</th></tr><tr><th>BR</th><th>MD</th><th>C</th></tr><tr><td>Low (≤30)</td><td>9.7 (6.7)</td><td>3.3 (3.9)</td><td>0.8 (5.4)</td></tr><tr><td>Moderate (31-38)</td><td>12.3 (10.1)</td><td>7.1 (5.6)</td><td>.9 (3.1)</td></tr><tr><td>High (>38)</td><td>24.2 (8.7)</td><td>2.0 (1.3)</td><td>1.0 (1.4)</td></tr></table></td><td>• Brief relaxation (BR) is effectively non-pharmacological approach and superior to music distraction (MD) in short term reduction in dental anxiety
• Relaxation techniques are a pragmatic, effective and cost saving method of facilitating dental treatment in anxious patients</td></tr>
</table>

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
				Group: BR vs C — HAQ (low anxiety), p-value: p<0.001; HAQ (moderate+ high anxiety), p-value: p=0.001 Group: MD vs C — HAQ (low anxiety), p-value: p=0.283; HAQ (moderate+ high anxiety), p-value: p=0.045 Group: BR vs MD — HAQ (low anxiety), p-value: p<=.003; HAQ (moderate+ high anxiety), p-value: p=0.008 • BR was more effective than MD • MD is beneficial in reducing state anxiety compared to control, the effect sizes were moderate. • BR was greatest effects among subjects with moderate anxiety	
Leo´n-Pizarro et al., (2007)	Relaxation Training (RT) and guided imagery techniques given 1 – 2 weeks prior to the hospitalization. • RT and Guided imagery given for 10 minute and were given cassette for use at home and at hospital.	RCT: • Hospital Anxiety and Depression Scale (HADS) • Quality of life: Cuestionario de Calidad de Vida QL-CAAFex (CCV) Assessment: Prior to the hospitalization, second day of hospitalization and 2/3 weeks after brachytherapy	Study among gynaecologic and breast cancer patients: • To determine the degree of anxiety and depression in patients with cancer during brachytherapy treatment •	**HADS-Depression** Prior: Study 4.58 (0.65); Control 4.94 (0.62); p-value 0.03 During: Study 3.74 (0.68); Control 5.91 (0.65) After: Study 3.26 (0.65); Control 5.12 (0.62) **HADS-Anxiety** Prior: Study 8.32 (0.77); Control 8.03 (0.73); p-value 0.008 During: Study 7.94 (0.76); Control 8.44 (0.72) After: Study 6.16 (0.72); Control 8.35 (0.68)	• Combination relaxation technique and guided imagery is effective in reducing the levels of anxiety, depression and body discomfort in patients undergoing brachytherapy

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
		Participants: • 32 intervention (22 gynaecologic + 10 breast) • 34 controls (25 gynaecologic + 9 breast)	To evaluate the effects of psychological intervention consisting in training in relaxation technique and guided imagery	**CCV:** • Significant reduction in Body Discomfort Scale (p=0.04). The Psychosocial Disorder Scale showed a reduction in the levels of alteration in the study group but not statistically significant (p=0.06)	
Yu et al., (2007)	Progressive muscle relaxation training (PMRT) • two PMRT sessions, • one revision workshop, • twice-daily PMRT home practices, • biweekly telephone follow-up Home visit held at 8th week (T2) and at the 14th week (T3)	Longitudinal RCT: Participants drew a slip without replacement from a bag. Assessment: • Hospital Anxiety and Depression Scale (HADS) Participants: • 59 interventions • 62 controls	Effect of PMRT on: Psychological distress and symptom status among older Chinese patients with heart failure	**HADS:** **Anxiety:** Intervention / Control / p-value Baseline 4.46 (3.32) / 3.44 (4.67) / p>0.05 8th week 2.95 (1.94) / 3.00 (2.05) 14th week 2.19 (1.56) / 2.84 (1.81) **Depression:** Baseline 11.22 (2.69) / 13.13 (3.66) / p<0.01 8th week 7.53 (2.58) / 10.55 (2.49) 14th week 6.53 (2.24) / 9.68 (2.76) Significant in time, group and time x group • Psychological distress: Significant reduction over the 14 week (p<0.001) – intervention group has significant greater improvement over time (p=0.001) • Depression subscale – significant reduction (F=30.0, p<0.005) • Anxiety subscale – no significant reduction (F=0.051, p>0.05). The result of repeated contrast of time also detected no significant group difference in the change of anxiety levels across the study end points.	• Patients practicing PMRT only demonstrated a non-significant trend of greater improvement in symptoms status. • PMRT is useful as an adjunctive non-pharmacological treatment in the management of heart failure • PMRT achieved a medium-size effect in reducing psychologic distress (partial $\eta 2 = 0.7$)

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

<table>
<tr><th>Authors</th><th>Type of treatment & duration</th><th>Study
Design & program
Participants</th><th>Treatment</th><th>Results</th><th>Conclusion</th></tr>
<tr><td>Bastami et al., (2005)</td><td>Applied Relaxation Muscle Training :
• seven 90-minute group education sessions over 7 weeks
• Baseline pre-intervention and post-intervention after 8 weeks</td><td>RCT:
Using a block randomization method

• Instruments:
• Spielberger State-
• Trait Anxiety Inventory
• Cohen Perceived Stress Scale

Participants:
• 110 primigravida in second and third trimester, at the end:
i. 55 interventions
ii. 55 controls</td><td>To investigate the effect of Applied PMRT on reducing state and trait anxieties and perceived stress among pregnant women.</td><td>STAI:
<table><tr><th></th><th>Experimental</th><th>Control</th></tr><tr><td>State-Anxiety:</td><td></td><td></td></tr><tr><td>• Pre-inter</td><td>37.18 (5.35)</td><td>38.58 (6.52)</td></tr><tr><td>• Post-inter</td><td>22.71 (7.38)</td><td>38.50 (5.73)</td></tr><tr><td>Trait-Anxiety:</td><td></td><td></td></tr><tr><td>• Pre-inter</td><td>35.65 (5.55)</td><td>37.58 (5.77)</td></tr><tr><td>• Post inter</td><td>22.71 (7.38)</td><td>38.50 (5.73)</td></tr></table>PSS:
<table><tr><th></th><th>Experimental</th><th>Control</th></tr><tr><td>• Pre-inter</td><td>31.29 (5.72)</td><td>30.98 (5.94)</td></tr><tr><td>• Post-inter</td><td>24.44 (5.84)</td><td>37.52 (5.67)</td></tr></table>• At post-test, significant decrease in experimental group compared to the control group (p<0.001)
• Experimental group showed significant reduction in mean PSS compared to pre-intervention score (p<0.001)
• A significant increase between pre and posttest scores in PSS for control group (p<0.001)</td><td>• APRT was effective in reducing both trait and state anxieties and perceived stress among pregnant women
• Teaching relaxation techniques could serve as a resource for improving maternal psychological health</td></tr>
<tr><td>Ozdemir & Pasinlioglu, (2009)</td><td>Training and Progressive Relaxation Exercises for 1 hour.</td><td>Quasi-experimental

Instrument:
• State-Trait Anxiety Inventory (STAI)

Participants:
• 34 experimental
• 32 control</td><td>To examine the effects of PMRT to anxiety level after hysterectomy</td><td>STAI:
<table><tr><th>Anxiety</th><th colspan="2">Experimental</th><th colspan="2">Control</th></tr><tr><td></td><td>Pre</td><td>Post</td><td>Pre</td><td>Post</td></tr><tr><td>State</td><td>40.9 (6.3)</td><td>27.6 (3.7)</td><td>41.1 (7.8)</td><td>40.4 (8.3)</td></tr></table>• Statistically reduction in the PMRT group (40.9 ± 6.3 and 27.6 ± 3.7) (p=0.001) but no significant in control group (40.4 ± 8.3 and 41.1 ± 7.8) (p=0.625) in post-pre test</td><td>• The Training and Progressive Relaxation exercise are effective in reducing of state anxiety</td></tr>
</table>

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
	• Encourage to perform at home every day or at least three times a week for 4 weeks by using the CD instruction.			• At the post test, there was significant different between intervention and control group (p=0.001)	
Hee et al., (2005)	Progressive muscle relaxation training (PMRT) + Guided Imagery (GI) 1 hour before chemotherapy • And on each of the next chemotherapy for a total six times • Practice at home using recorded tape	RCT • Randomly allocated by simple random sampling. • Randomization was carried out by using the envelope method Instruments: • Multiple Affective Adjective Checklist (MAACL) for Anxiety and Depression • Functional Assessment of Cancer Therapy – Breast (FACT-B)	Anticipatory nausea and vomiting (ANV) and post-chemotherapy nausea and vomiting (PNV) and QOL among breast cancer patients after six cycles of cyclophosphamide, methotrexate and 5-fluorouracil (MWF)	MAACL, patients' records of ANV immediate before CT and follow-up record of PNV **PMRT + GI** / **Control,** / **p-value** **a) MAACL** Anxiety: 7.01 (3.81) / 9.75 (3.48) / Group ($p<0.01$), Session ($p<0.01$) Depression: 7.32 (7.21) / 15.62 (5.52) / Group ($p<0.001$) **b) Record of ANV** Anxiety: 1.52 (1.21) / 2.67 (1.40) / Group ($p<0.01$) **c) Follow-up home record of PNV** Anxiety: 1.11 (1.03) / 2.27 (1.31) / Group ($p<0.001$) • During the six sessions, there were significant between-group differences in patients' anxiety and depression, but anxiety also showed a significant session effect.	• Combination PMRT + GI was significantly less anxious and depressive than control group • 6 months after chemotherapy, the QOL of PMRT + GI was higher than control group • PMRT and GI were associated with both the improvements in anticipatory and post chemotherapy nausea and vomiting and in the QOL of breast cancer patients

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

<table>
<tr><th>Authors</th><th>Type of treatment & duration</th><th>Study Design & program Participants</th><th>Treatment</th><th>Results</th><th>Conclusion</th></tr>
<tr><td></td><td></td><td>Participants:
• 30 (PMRT + GI)
• 30 control</td><td></td><td>Effects of PMRT and GI on the QOL
• After 3 months: only EWB showed significant different
• After 6 months: PWB (p<0.05), EWB (p<0.05), BCS (p<0.05) and FACT-B (p<0.05) showed significant different</td><td></td></tr>
<tr><td>Pawlow & Jones (2002)</td><td>Twice 20 minutes Abbreviated Progressive Relaxation Training spaced 7 days apart. Provided a tape to practice at home</td><td>Experimental study. Gender-matches pairs

Instruments:
• STAI state,
• Cognitive manifestations of anxiety (CSAQ-Cognitive), Cognitive manifestations of anxiety (CSAQ-Somatic),
• PSS

Participants:
• 44 experimental (22 male + 24 females)
• 15 control (8 females + 7 males)
• 5.4 days for the experimental group did relaxation at homes</td><td>• Anxiety, stress, heart rate, finger pulse volume, cortisol level - 24 years old undergraduate students</td><td>The mean difference (score) of self-report by group, day and time (* Significant at α=0.05)
<table><tr><th></th><th colspan="2">Experimental</th><th colspan="2">Control</th></tr><tr><td></td><td>Day 1</td><td>Day 8</td><td>Day 1</td><td>Day 8</td></tr><tr><td>STAI</td><td>-12.1*</td><td>-8.8*</td><td>-0.3</td><td>-3.2</td></tr><tr><td>PSS</td><td>-1.7*</td><td>-1.3</td><td>1.6</td><td>0.5</td></tr><tr><td>CASQ-C</td><td>-0.1</td><td>-0.9</td><td>-1.0</td><td>-1.6*</td></tr><tr><td>CASQ-S</td><td>-1.1*</td><td>-0.9</td><td>-0.4</td><td>-0.6</td></tr><tr><td>Relax</td><td>3.1*</td><td>3.0*</td><td>0.0</td><td>0.2</td></tr></table>STAI state:
• Significant main effects for time (pre and post) (F=50.35, p<0.01) and for group (F=8.04, p<0.01)
• experimental group reported a significant decrease in level of state anxiety from pre to post-relaxation session, (F=75.96, p<0.01), the control participants did not significantly differ in their levels of state anxiety from pre- to post session

CSAQ (Cognitive)
• Significant main effect for time (F=12.38, p=0.001). Subjects generally tended to report fewer cognitive manifestations of anxiety at the end (M=14.4) of a session as compared to the beginning of a session (M=15.1)</td><td>• The brief relaxation exercise in the experimental group had significantly lower levels of post-intervention state anxiety, perceived stress as well as increased levels of self-report</td></tr>
</table>

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
				CSAQ (Somatic) • Overall, subjects reported less somatic anxiety (F=8.10, p=0.006) at the end of a session (M=12.7) as compared to the beginning of a session (M=13.6) **PSS:** • Experimental subjects reported a significantly reduced level (F=8.01, p<0.001), while control had no significant effect from pre- to post-session **Relaxation:** A significant main effect for time (pre vs post), F(1,59) = 75.36, p<0.001 and for groups, F(1,59) = 4.29, p<0.05.	
Pawlow et al., (2003)	Two 20-min Abbreviated Progressive Muscle Relaxation (APMR) with 7 days apart. Posttest at day 8.	Randomly assigned Instruments: • State-Trait Anxiety Inventory (STAI) Perceived Stress Scale (PSS) • Beck Depression Inventory (BDI) Participants: • Experimental: 44 • Control: 15	Stress, mood, hunger and eating pattern among night eating syndrome patients (subjective and physiological stress)	**STAI:** • Experimental group significantly lower than Controls on State Anxiety scores at Day 1 post-session (F=15.90, p<0.01) and at Day 8 pre-session (F=12.06, p<0.01). • There were also significant decreases over time in the Experimental group (F=11.62,p<0.01) but not in the Control group **Perceived stress.** • Experimental was significantly lower than the Controls on at Day 1 post-session (F=4.69, p<0.05) and at Day 8 pre-session (F=8.19, p<0.01). • There were also significant decreases over time in the Experimental group (F=6.89, p<0.01) but not in the Control group .	20 minutes of muscle relaxation exercise significantly reduce stress, anxiety and depression post-session • After practicing for a week, subject exhibited lowered stress, anxiety and depression at day 8

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

<table>
<tr><th>Authors</th><th>Type of treatment & duration</th><th>Study Design & program Participants</th><th>Treatment</th><th>Results</th><th>Conclusion</th></tr>
<tr><td></td><td></td><td></td><td></td><td>BDI:
Experimental was significantly more depressed than the Controls on Day 1 (F=5.13, p<0.05), but not on Day 8.
There was a significant decrease in depression from Day 1 to Day 8 for the Experimental (F=7.19, p<0.025) but not the Control group</td><td></td></tr>
<tr><td>Navaneethan & Soundararajan (2010)</td><td>PMR Training for 3 days a week and for 6 weeks in total</td><td>Experimental study. Player were randomly allocated:

Instrument:
Competitive State Anxiety Inventory-2 (CSAI-2) administered 10 minutes before competition and practice lesson
Participants:
12 intervention
12 control</td><td>Anxiety before the inter-collegiate volleyball competition (18 to 25 years old)</td><td>CSAI-2<table><tr><th>Variable</th><th colspan="2">Intervention</th><th colspan="2">Control</th></tr><tr><th></th><th>Pre</th><th>Post</th><th>Pre</th><th>Post</th></tr><tr><td>Cognitive anxiety</td><td>21.50</td><td>20.08</td><td>21.15</td><td>20.85</td></tr><tr><td>Somatic Anxiety</td><td>22.08</td><td>20.50</td><td>21.25</td><td>20.85</td></tr><tr><td>Self Confidence</td><td>21.25</td><td>22.75</td><td>21.50</td><td>21.75</td></tr></table>
Players belong to progressive relaxation training is performed better in cognitive anxiety (mean diff.: 1.42,p<0.05), somatic anxiety (mean diff.: 1.58,p<0.05) and self-confidence (mean diff: -1.50, p<0.05) as compared to before intervention
Player in control group found to be no significant differences in cognitive anxiety (mean diff: 0.30, p>0.05), somatic anxiety (mean diff: 0.40, p>0.05) and self-confidence (mean diff: -0.25, p>0.05)</td><td>Progressing from a tensed state to relaxation helps to develop the ability to recognize and differentiate the feeling of tension and relax the muscle
Relaxation improves alertness and awareness in such a way that the performance will be maximized</td></tr>
</table>

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
Mackereth et al., (2009)	Combination of Progressive Muscle relaxation training (PMRT) and reflexology • Received 6 weekly PMRT (40 minutes per session), followed 4 week 'washout' break then 6 sessions of weekly reflexology (Ingham method)	• A two crosses over trial design with a washout period (4 weeks) to prevent treatment contamination • Convenient sampling. Instruments: • Health status : SF-36, GHQ-28 • Anxiety : State Anxiety Inventory (SAI) Participants: • Group 1 = 25 (20 males + 5 females) • Group 2 = 25 (18 males + 7 females)	Aim: • Do the intervention affect / improve the patients' health / well-being among multiple sclerosis patients (27 to 76 years old)	**SF-36** **HRQOL** / **Mean change (95%CI)** / **p-value** Physical function: 4.28 (1.418, 7.142) / 0.004 Role emotional: 12.0 (3.999 – 20.000) / p=0.0004 mental health: 5.94 (3.153 – 8.727) / p<0.001 Vitality: Weak effect / 0.025 • The other domains were not significant improvement **GHQ-28 (subscale):** • Anxiety and insomnia (p<0.001, 95% CI: 1.25 – 2.59) item shown significant reduction different • Severe depression (95%CI: 0.552-1.748), somatic symptoms (95% CI: 0.428-2.172) and social dysfunction (95% CI: 0.461 – 2.119) items did not showed significant differences reduction **SAI:** • Drop significantly (p<0.001, mean value: 8.093,95% CI: 6.627 – 9.559)	• There was a positive effects of both treatments following sessions and over the 6 weeks of treatment in MS patients • There was some potential in MS patients to be helped by PMR training • No overall differences between intervention as measures by SF-36 and GHQ-28 with assessment, difficult for some variable due to interaction between order and treatment.
Boyce et al., (2003)	Cognitive Behaviour Therapy (CBT), Relaxation Training (RT) and Routine Clinical Care (RCC)	RCT – a series of sealed opaque envelopes containing card with the treatment conditions.	• to compare cognitive behavior therapy with relaxation	**SF-36 (mean score of all domain):** **Base** / **4-wk** / **8-wk** / **26-wk** / **52-wk** PF: 79.4 / 87.2 / 90.0 / 92.9 / 91.9 RP: 45.7 / 80.4 / 72.2 / 72.1 / 75.0 BP: 53.0 / 68.7 / 63.7 / 64.8 / 64.2 GH: 59.7 / 58.7 / 61.7 / 68.1 / 65.9	• There were no significant different among the three treatment conditions.

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
	• CBT: three 15-30 minutes • session + receive standard dietary advice by gastroenterologist • RT: weekly 30-min, face-to-face, instructional sessions for 8 wk • CBT: manual-based program on the hypochondriasis model of Salkovskis and the CBT approach.	Instruments: SF-36 HADS Participants: • RCC = 34 • RT = 36 • CBT = 35	therapy and routine clinical care alone in • individuals with IBS without a comorbid psychiatric diagnosis. • The primary outcome for this study was bowel symptom severity for the Irritable bowel syndrome	<table><tr><th></th><th>Base</th><th>4-wk</th><th>8-wk</th><th>26-wk</th><th>52-wk</th></tr><tr><td>VT</td><td>48.0</td><td>63.7</td><td>59.7</td><td>60.6</td><td>61.5</td></tr><tr><td>SF</td><td>66.1</td><td>84.2</td><td>83.1</td><td>81.9</td><td>76.9</td></tr></table> • Significant changes over time were found for the physical functioning (F=4.37, p<0.001), pain (F=3.12, p<0.05), general health (F=2.71, p<0.05), vitality (F=2.94, p<0.05), and the social functioning scales (F=4.08, p<0.05), with all subject groups showing improvement in their functional impairment over time • There were no significant changes over time on the physical role (F=2.33, ns), role-emotional (F=1.54, ns), and mental health (F=1.16, ns) subscales. • The greatest improvement on the pain subscale was for participants in the RCC group, with that group returning a significantly higher score at completion of treatment (F=4.44, p<0.05); • Similar results were obtained using an ITT analysis with significant improvement in physical functioning (F=5.55, p<0.001), physical role (F=4.25, p<0.01), pain (F=6.12, p<0.001), vitality (F=7.77, p<0.001), general health (F=4.03, p<0.01), and social functioning (F=6.47, p<0.001). • There were no differences found for mental health (p>0.05) or emotional role (p>0.05)	Significant changes seen over time found for: i. Physical functioning, ii. pain, iii. general health, iv. vitality and v. social functioning • Overall, all three treatment showed similar improvement There were significant reductions in anxiety, depression but no significant differences among treatment groups detected.

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
				HADS: **Base** / **4-wk** / **8-wk** / **26-wk** / **52-wk** HAD: anxiety: 8.6 / 6.7 / 7.0 / 6.2 / 7.1 HAD: depression: 5.4 / 3.5 / 4.2 / 3.4 / 3.6 There were no differences in the means scores on the HAD, but some differences emerged. • 19 (55.9%) of the CBT participants scored above the cut-off, compared to 11 (32.4%) RCC and 10 (27.8%) of the RT participants ($p<0.05$). • A higher proportion of CBT participants scored above the cut-off on the depression subscale (CBT [14.7%], RCC [5.9%], and RT [8.3%],($p>0.05$) but this difference was not significant.There was a reduction in the HAD scale ($F=4.67$, $p<0.001$) with both significant reduction in anxiety and depression.	
Rashid & Parish (1998)	Behavioural relaxation training (BRT), progressive muscle relaxation (PMR) in comparison with control.	Not mention study design Instrument: • State-Trait Anxiety Inventory (STAI)	• To assess the anxiety level among High school student.	**STAI:** • a significant treatment effect ($F=5.99$, $p<0.005$), but no significant gender effect ($F=1.66$, $p>0.05$) • No significant interaction effect ($F=1.80$, $p>0.05$) • BRT (mean: 37.33) and PMRT (mean: 37.75) scores did not vary significantly from one another, but were both significantly lower than control group (mean: 44.53) • Variance failed to reveal any significant differences as a function of treatment ($F=0.61$, $p>0.05$)	• BRT and PMR were capable of helping high school students to reduce their state anxiety but cannot comment on trait anxiety.

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
	• BRT + PMR – videotaped instruction given of the appropriate relaxation technique. • Four 20-minutes training sessions in two weeks • The day after the last treatment all the group were asked to complete STAI	Participants: • BRT = 18 (9 males + 9 females) • PMRT = 20 (9 males + 11 females) • Control = 17 (8 males + 9 females) Response rate: 62.5%			• State anxiety is more transient, whereas trait anxiety is part of one's personality make up, and therefore more resistant to change.
Sloman (2002)	Comparison between progressive muscle relaxation (PMR) and Guided Imagery (GI) • Only one session with the participants • Tape recorder given to practice at home twice daily	Randomize pretest-posttest control group clinical trial. Instruments: • Hospital Anxiety and Depression Scale (HADS) • Functional Living Index – Cancer Index i.	To compare the effect of PMR and GI on anxiety depression and QOL in people with advanced cancer • 26 females • 30 males • Mean age: 54.5 • Age range 27 - 79	**Anxiety:** • None of the 3 treatment produced significant reduction (F=2.678, p=0.057) • No any significant moderators' effect; diagnosis (F=0.1.528), gender (F=0.116), level of education (F=2.030) or age (F=2.300) **Depression:** • All 3 treatments produced a significant reduction in depression (F=4.639, p<0.001) • No significant effects were found; diagnosis (F=0.161), gender (F=0.794) • No significant interaction effect • No significant difference between treatment group in multiple comparisons of means	• There were a significant changes occurred for depression and quality of life. However, no significant improvement for anxiety

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
	• Follow up appointment twice weekly • Post testing 3 weeks after the initial session	Participants: • 56 participants randomly assigned to: ii. PMR only iii. GI only iv. PMR + GI v. Control		**Quality of Life (QOL)** • There was a significant groups effect for QOL (F=4.979, p<0.001) • No significant interaction • Multiple comparisons of means showed all the 3 treatments groups differed significantly from control but not from each other.	
Ghafari et al., (2009)	PMRT: • Training in PMRT for 16 days for all groups. • 3 days training of instructional PMRT CD to train at home for 8 weeks	Quasi–experimental • No probability sampling was carried out • participants were divided randomly in two experimental and control groups Instrument: • SF-8 Health Survey (used for 3 times (at the beginning, 4 weeks after intervention and at the end of eight weeks)	To investigate and determine the effect of PMRT on QOL of the patients with multiple sclerosis age 20–45	**SF-8 QoL:** **PCS-8:** • Before 29.64 29.16 • 1-mth later 35.61 27.14 • 2-mth later 42.07 26.95 **PCS-8:** • Before 29.64 29.16 • 1-mth later 35.61 27.14 • 2-mth later 42.07 26.95 **MCS-8:** • Before 28.54 28.45 • 1-mth later 35.52 25.79 • 2-mth later 40.47 25.79	• PMRT is feasible and is associated with increase the QOL among MS patients at 4 weeks and 8 weeks post intervention • Age correlated with lower quality of life • The PCS and MCS increased significantly different by three times

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
		Participants: • 33 experimental • 33 controls		• four weeks after intervention, this difference between control and experimental groups was significant in PCS-8 ($p<0.0001$) and MCS-8 ($p<0.0001$) • at 8 weeks, significant difference between control and experimental groups in PCS-8 ($p<0.001$) and MCS-8 ($p<0.001$) • Life quality level has been increased both in PCS-8 and MCS-8 scores of quality of life in experimental group • Repeated measures of Analysis of Variance (ANOVA) showed that there is a significant difference between total, PCS-8 and MCS-8 mean scores of quality of life between experimental and control groups four and eight weeks after intervention ($p<0.05$) • There was a significant difference in mean score of whole and dimension of HRQOL between two groups in three times ($p<0.05$)	
Gill et al., (2004)	Comparing Benson's relaxation method (BRM) and progressive relaxation (RT) On the first day, one group completed the PT while the other group completed BRM).	Randomly assigned to one of two groups a priori stratified by gender Instrument: Competitive State Anxiety Inventory-2 (CSAI-2) Participants: • 76 (46 female and 30 male)	Undergraduate physical therapy student (age 17 to 29 years old) (mean age 19.2 ± 1.9)	**Comparison of the effect of Benson's vs progressive on cognitive and somatic anxieties** Change in cognitive anxiety: (z / p-value) • Session 1: -0.083 / 0.934 • Session 2: -0.083 / 0.532 • Session 1 and 2: -0.090 / 0.930 Change in somatic anxiety: • Session 1: -0.172 / 0.864 • Session 2: -0.530 / 0.596 • Session 1 and 2: -1.591 / 0.112	Both Benson's relaxation method (BRM) and Progressive relaxation (PR) were effective in reducing cognitive and somatic anxiety and alleviating self-confidence.

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

<table>
<tr><th>Authors</th><th>Type of treatment & duration</th><th>Study
Design & program
Participants</th><th>Treatment</th><th>Results</th><th>Conclusion</th></tr>
<tr><td></td><td>• On the second day (1 week later) the intervention reversed.</td><td></td><td></td><td>Comparison of pre and post CSAI-2:
<table><tr><th>Anxiety:</th><th colspan="2">Benson's</th><th colspan="2">Progressive</th></tr><tr><td></td><td>z</td><td>p-value</td><td>z</td><td>p-value</td></tr><tr><td>• Cognitive</td><td>-5.242</td><td><0.001</td><td>-4.583</td><td><0.001</td></tr><tr><td>• Somatic</td><td>-5.614</td><td><0.001</td><td>-5.096</td><td><0.001</td></tr></table></td><td>• There appeared to be no significant differences between the effects of either technique on cognitive and somatic anxieties.</td></tr>
<tr><td>Dehdari et. al., (2009)</td><td>PMR training for 6 weeks.
• Twelve – 40 minutes over 6 weeks.
• All patient followed up one month after intervention
• A CD provided to help for a home practice</td><td>Experimental study. Patients were randomly allocated

Instruments:
• Anxiety : State-Trait Anxiety Inventory (STAI)
• QOL: SF-36

Participants:
• 55 relaxation group (74.5 men + 25.5 females) : exercise training + lifestyle education + relaxation
• 55 control (69.2 males + 30.9 females) : exercise training + lifestyle education</td><td>Anxiety and quality of life after coronary artery bypass graft surgery patients</td><td>STAI:
<table><tr><th>Anxiety</th><th colspan="2">Relaxation group (N=55)</th><th colspan="2">Control group (N=55)</th></tr><tr><td></td><td>Before</td><td>After</td><td>Before</td><td>After</td></tr><tr><td>State</td><td>50.7 (8.6)</td><td>34.9 (1.4)</td><td>48.6 (19.5)</td><td>44.9 (4.1)</td></tr><tr><td>Trait</td><td>49.6 (9.1)</td><td>38.0 (1.2)</td><td>48.2 (9.2)</td><td>45.3 (10.6)</td></tr></table>• Significant reduction in state anxiety (p<0.01) and trait anxiety (p<0.01) levels were observed in relaxation group after intervention compared to control group
• Women had higher state anxiety (p<0.05) compare to man,

SF-36:
<table><tr><th>HRQOL</th><th colspan="2">Relaxation group (N=55)</th><th colspan="2">Control group (N=55)</th></tr><tr><td></td><td>Before</td><td>After</td><td>Before</td><td>After</td></tr><tr><td>PF</td><td>59.4 (21.2)</td><td>85.6 (13.0)</td><td>54.7 (17.8)</td><td>68.7 (17.0)</td></tr></table></td><td>• No significant association among age, marital situation and educational level with : state and trait anxiety and QOL
• PMRT may effective for improving psychological outcomes and QOL with clinical levels of anxiety after CABG surgery</td></tr>
</table>

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
				HRQOL: **Relaxation group** (N=55) / **Control group** (N=55) RP: 21.3 (24.3) / 47.2 (30.3) / 19.0 (25.4) / 34.5 (30.6) BP: 40.5 (22.9) / 71.8 (17.7) / 43.4 (24.2) / 55.7 (24.2) GH: 61.1 (18.0) / 78.1 (15.2) / 59.2 (17.8) / 62.3 (20.2) VT: 42.5 (20.9) / 66.6 (18.8) / 47.1 (17.8) / 51.2 (20.3) SF: 52.5 (27.4) / 81.3 (22.8) / 54.5 (25.2) / 64.7 (28.2) RE: 27.8 (28.5) / 74.5 (31.4) / 29.8 (29.1) / 47.2 (6.6) MH: 51.7 (21.4) / 76.3 (16.0) / 56.0 (19.7) / 57.8 (20.8) • All domains of QOL in the relaxation group were significantly more compared to the control group after intervention. • Women had lower overall QOL ($p<0.005$) compared to man.	
Berggren et al., (2000)	Relaxation therapy (RT) + phobia therapy + dental treatment vs	Did not mention the study design – just say randomly assign:	For phobic dental fear at the specialized Dental Fear Research and Treatment Clinic (DFRTC)	**Instruments** / **Relaxation therapy** / **Cognitive therapy** / **p-value** **DAS:** Before: 17.0 (2.3) / 17.6 (2.1) / 0.001 After phobia Tx: 11.5 (3.3) / 13.4 (4.0) After dental Rx: 8.6 (3.2) / 9.8 (3.8)	• RT and COT were both effective in reducing dental phobic reactions

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
	Cognitive oriented therapy (COT) + phobia therapy + dental treatment Random tape recording from therapy session • Both treatment used a video-based hierarchy of eight dental scenes and consisted on a maximum of eight therapy session.	Instruments: • State Trait Anxiety Inventory (STAI) • Dental Anxiety Scale (DAS) Participants: • Relaxation therapy: 54 (12 men + 42 women) • Cognitive therapy: 58 (18 men + 40 women)		**Instruments** / **Relaxation therapy** / **Cognitive therapy** / **p-value** **STAI-S:** Before: 37.9 (12.0) / 41.1 (10.1) / 0.001 After phobia Tx: 32.9 (11.8) / 38.1 (12.2) After dental Rx: 31.1 (13.8) / 34.5 (12.7) **STAI-T:** Before: 37.6 (12.0) / 38.4 (11.0) / 0.001 After phobia Tx: 35.2 (10.5) / 37.5 (9.7) After dental Rx: 30.9 (10.4) / 36.1 (9.4) **STAI-S:** Post-treatment: RT (31.1±13.8) vs COT (34.5±12.7) (F=8.68, p=0.001) **STAI-T:** Post-treatment: RT (30.9±10.4) vs COT (36.1±9.4) (F=14.89, p=0.001) **DAS:** Post-treatment: RT (8.6±3.2) vs COT (9.8±3.8) (F=232.22 p=0.001)	• Relaxation-orientated treatment has more significant reduction in dental fear as well as in general anxiety and fear • Motivation be a significant predictor of successful treatment outcome
Cheung et al., (2003)	PMR Training for 20 minutes in combination with deep breathing • Excluded training of abdominal muscle to reduce the incidence of increased intra-abdominal pressure	RCT: Randomization using envelope method Instruments: • The Chinese version of the State-Trait Anxiety Inventory (C-STAI) • QOL Index for Colostomy	To determine the effectiveness of PMRT in reducing anxiety and improving quality of life among colorectal patients after stoma surgery.	**State-Anxiety:** **Experimental** / **Control** T1: 54.65 (2.57) / 51.03 (10.96) T2: 40.79 (2.28) / 44.26 (5.97) T3: 31.27 (3.17) / 42.83 (4.24) R-ANOVA: • Group: F(1,57)= 8.99, p<0.01 • The experimental group reporting a significantly lower state anxiety compared to control group • A significant time effect was observed with the score decreasing over 10 weeks for subject in both groups	• PMRT significantly decreased state-Anxiety and improved generic QOL mostly in physical health, psychological health, social concerns and environment.

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion
	• One briefing and one training session postoperative period • CD given to practice at home for at least 2-3 times per week for 1 week	• Hong Kong Chinese version of the WHO-QOL Measure-Abbreviated Version • Medical-social-demographic data Participants: • 30 interventions • 29 controls		**QOL-disease specific measure:** **Experimental** / **Control** T1: 99.29 (19.56) / 97.11 (27.24) T2: 108.63 (17.75) / 108.07 (14.36) T3: 129.37 (14.06) / 110.31 (15.22) R-ANOVA: • Group: $F(1,57)=2.63$, $p>0.05$. No significant difference over the time • Time: $F(2,56)=35.96$, $p<0.001$. A significant time effect observed with the scores increasing over 10 weeks for both group. In relation to domain: • Physical health ($F=7.12$, $p<0.01$) • Psychological health ($F=4.50$, $p<0.05$) • Social concerns ($F=4.21$, $p<0.05$), • General QOL ($F=9.29$, $p<0.01$)	• For disease-specific QOL measure, experimental group performed better at 10 weeks but not over time • PMRT should incorporate in the long-term care of colorectal cancer patients. • PMRT may be a cost-effective intervention that needs minimal training. • Social relationship decreased in both groups • PMRT should be incorporated in the long term care • Patients who had practice PMRT more frequently reported lower state anxiety and higher QOL

Table 2.7: Progressive muscle relaxation studies for depression, anxiety, stress and health-related quality of life (continue)

Authors	Type of treatment & duration	Study Design & program Participants	Treatment	Results	Conclusion

QOL-generic scale:

	Experimental	Control
T1	75.65 (3.93)	77.10 (18.10)
T2	95.27 (4.18)	82.23 (9.52)
T3	104.10 (5.41)	85.13 (5.82)

R-ANOVA:

- Group: $F(1,57)= 26.52$, $p<0.001$. A significant difference between intervention and control groups.
- Time over 10 weeks: $F(2,56)= 97.63$, $p<0.001$. A significant time effect with the scores decreasing over 10 weeks
- There were significant differences to all domains of WHO-QOL scale with experimental group reporting significantly higher ratings
-

Correlation between frequency of practicing APMRT, state anxiety and QOL at 5 and 10 weeks

	Frequency of practice PMRT	p-value
State anxiety (week 5)	-0.62	<0.001
State anxiety (week 10)	-0.49	<0.001
QOL-colostomy scale (week 5)	-0.31	<0.05
QOL-colostomy scale (week 10)	0.08	>0.05
QOL-Generic (week 5)	0.59	<0.001
QOL-Generic (week 10)	0.88	<0.001

2.4.10.1 Demographics

Table 2.7 summarizes the studies selected for systematic review. Twenty two articles were identified with 18 clinical and six non-clinical studies. The clinical studies were conducted among patients with schizophrenia, somatoform heart disease; heart failure, dental anxiety and phobia, port stoma and coronary artery bypass graft surgeries, gynaecologic, breast and advanced cancers, pregnancy and post hysterectomy, multiple sclerosis, irritable bowel and night eating syndromes. For the non-clinical studies, these were conducted among healthy young undergraduates and high school students, volleyball players and the community.

2.4.10 .2 Types of intervention

The studies have been conducted to observe the impact of various relaxation techniques either comparing with other relaxation techniques (e.g. Yoga, guided imagery, music distraction, cognitive behaviour therapy, behavioural relaxation therapy, cognitive orientated therapy and Benson's relaxation method) or in combination with other relaxation therapy (eg. reflexology and phobia therapy). There were two studies comparing relaxation therapy with other relaxation techniques, 12 studies comparing relaxation therapy with control (placebo) and five studies comparing relaxation therapy with other relaxation techniques and control (placebo). There were three studies conducted by using a combination of relaxation therapies with other relaxation techniques and compared to control (placebo).

2.4.10.3 Study designs

There were various study designs used to assess the impact of the relaxation therapy. In this systematic review 59.1 percent were conducted using randomized controlled trial (RCT) and 9.1 percent used quasi-experimental study design. There were 18.1 percent of the studies which did not clearly state the study designs. There was one cross over trial design and two studies did not mention the type of study design.

2.4.10.4 The frequency, duration and length of intervention given

The average frequency for relaxation therapy given was 7.76 times (range: 1 – 18 times). However, there were five studies which did not mention the frequency of their study. The average duration for each relaxation therapy given was 39 minutes (range: 10 minutes – 90 minutes). However, seven studies did not mention the duration of the relaxation therapy given. The average intervention length was 4.25 weeks (range: 1 week – 10 weeks).

2.4.10.5 Sample size

The total sample size was 1591 and the average sample size was 72.3 (range: 14 – 121). The average number of participants in the relaxation therapy group was 35.9 (range: 8 – 59), meanwhile, the average participants in the control group was 30.7 (range: 6 – 62). The average number of participants in the other relaxation technique group was 40.8 (range: 18 – 65), meanwhile, the average participant using in a combination of relaxation therapy and other relaxation techniques was 30.3 (range: 11 – 50).

There were 354 male and 483 female participants involved in the studies. However, the 11 studies did not mention the total number of male and female participants.

2.4.10.6 Instruments

The instrument used to assess the scoring for depression, anxiety, stress HRQOL varied. There were four studies which assessed specific QOL and five studies assessed generic QOL. The distribution of the instruments used for the quality of life assessment is shown in Table 2.8

Table 2.8 : Distribution of the instruments used for the quality of life assessment

Type	Instruments	Frequency (%)
Generic	SF-36	3 (33.3)
	SF-8	1 (11.1)
	SF-6	1 (11.1)
Specific	Functional Living Index – Cancer Index	1 (11.1)
	Functional Assessment of Cancer Therapy (FACT)	1 (11.1)
	Quality of life: Cuestionario de Calidad de Vida	1 (11.1)
	QOL-colostomy Hong Kong WHOQOL	1 (11.1)

There were seven studies assessed for depression, while 21 studies assessed for anxiety and four studies assessed for stress. The distributions of the instruments used for assessing depression, anxiety and stress assessment are shown in Table 2.9.

Table 2.9 : Distribution of the instruments used for assessment of depression, anxiety and stress.

Type	Instruments	Frequency (%)
Depression	Hospital Anxiety Depression Scale (HADS)	4 (57.1)
	Somatization and Anxiety of the symptom Checklist of Derogatis (SCL-90)	1 (14.3)
	Multiple affective Adjective Checklist (MAACL-Depression)	1 (14.3)
	Beck Depression Inventory (BDI)	1 (14.3)
Anxiety	State-Trait Anxiety Inventory (STAI)	11 (50.0)
	Hospital Anxiety Depression Scales (HADS)	4 (18.2)
	Competitive State Anxiety Inventory (CSAI)	2 (9.2)
	Beck Anxiety Inventory (BAI)	1 (4.5)
	Somatization and Anxiety of the symptom Checklist of Derogatis (SCL-90)	1 (4.5)
	STAI Hierarchial Anxiety Questinnaire (HAQ)	1 (4.5)
	Dental Anxiety Scale (DAS)	1 (4.5)
	Multiple affective Adjective Checklist (MAACL-Anxiety)	1 (4.5)
Stress	Perceived Stress Scale (PSS)	3 (75.0)
	Visual Analogue Scale Stress (VASS)	1 (25.0)

2.4.10.7 The outcomes

There were nine studies assessing for generic and specific quality of life. All relaxation studies showed significant improvement. In assessing generic quality of life, it improved among the Australian community (Smith et al., 2007), multiple sclerosis patients (Ghafari et al., 2009; Mackereth et al., 2009), post coronary artery bypass graft patients (Dehdari et al., 2009) and irritable bowel disease patients (Boyce et al., 2003). For quality of life, it improved among gynaecological and breast cancer patients (Leo´n-Pizarro et al., 2007), breast cancer patients who underwent

chemotherapy (Yoo et al., 2005), patients with advanced cancer (Sloman, 2002) and post stoma colorectal patients (Cheung et al., 2003)

All four studies assessing stress levels showed significant improvement. It indicates that relaxation therapy is effective in reducing stress among healthy young adults (Emery et al., 2008), pregnant women (Bastani et al., 2005), undergraduate students (Pawlow & Jones, 2002) and night eating syndrome patients (Pawlow et al., 2003).

There were seven studies involved in assessing depression level. Only five studies showed significant improvement after relaxation therapy was implemented. It was found that relaxation therapy showed significant improvement among undergraduate students (Pawlow & Jones, 2002), gynaecological and breast cancer patients (Leo´n-Pizarro et al., 2007), breast cancer patients who underwent chemotherapy (Yoo et al., 2005), heart failure patients (Yu et al., 2007) and high school students (Rashid & Parish, 1998). However, relaxation therapy did not show any advantage among patients with irritable bowel disease (Boyce et al., 2003) and somatoform heart disorder patients (Lahmann et al., 2008a).

A total of 21 studies were involved in assessing anxiety level of which 18 studies showed significant improvement whereas three studies showed no improvement. In clinical setting, relaxation therapy was found to be effective to reduce anxiety level among schizophrenic patients (Chen et al., 2009), night eating syndrome patients (Pawlow et al., 2003), multiple sclerosis patients (Mackereth et al., 2009), somatoform heart patients (Lahmann et al., 2008a), post coronary artery bypass graft patients (Dehdari et al., 2009) and post hysterectomy patients (Ozdemir & Pasinlioglu, 2009). Relaxation therapy reduced the anxiety of breast cancer patients undergoing chemotherapy (Yoo et al., 2005), gynaecological cancer (Leo´n-Pizarro et

al., 2007) and post stoma colorectal cancer patients (Cheung et al., 2003). Relaxation therapy was also effective in reducing anxiety and fear among dental patients (Lahmann et al., 2008b) and phobic dental patients (Berggren et al., 2000).

In the non-clinical setting, relaxation therapy was found to be effective in reducing the anxiety level among undergraduate students (Gill et al., 2004; Pawlow & Jones, 2002), high school students (Rashid & Parish, 1998) and among Australian community (Smith et al., 2007). The relaxation therapy improves alertness and awareness among athletes, this can be maximized during tournaments (Navaneethan & Soundara Rajan, 2010). However, relaxation therapy did not significantly decrease the anxiety level among older Chinese patients with heart failure (Yu et al., 2007), irritable bowel syndrome (Boyce et al., 2003) and patients with advanced cancer (Sloman, 2002).

Comparing with other alternative treatment, relaxation therapy was found to be more effective compared to music distraction in reducing dental anxiety in the short term duration (Lahmann et al., 2008b). However, yoga was found to be more effective than relaxation in improving mental health (Smith et al., 2007). Combination relaxation technique and guided imagery were effective in reducing the levels of anxiety, depression and body discomfort in patients undergoing brachytherapy (Yoo et al., 2005). The combination between relaxation and reflexology was effective in quality of life over the six weeks treatment in multiple sclerosis patients (Mackereth et al., 2009).

2.4.10.8 Conclusion

A considerable number of published studies succeeded in showing that progressive muscle relaxation is beneficial in decreasing depression, anxiety, stress and improving quality of life. It is not surprising that in the last decade many researchers have turned their attention to other non-pharmacological treatment for psychological problems. However, not many studies showed the effect size therefore, the real impact of relaxation therapy was not known clearly although there was statistically significant improvement.

CHAPTER 3: METHODOLOGY

3.1 Study Design

This was a quasi-experimental study with mixed design repeated measure analysis of variance (ANOVA) where there was one intervention group with applied progressive muscle relaxation training (APMRT), while the comparison group was given information about depression, anxiety and stress and minimal health education. Comparison was made between these groups at baseline, 4-month and 6-month. Pre and post-intervention measurements for both groups was obtained.

3.2 Location of Study

Two tertiary medical centers selected for this study were University Malaya Medical Centre (UMMC) and Universiti Kebangsaan Malaysia Medical Centre (UKMMC). UMMC is a teaching hospital for University of Malaya and UKMMC is a teaching hospital for *Universiti Kebangsaan Malaysia* (National University of Malaysia). Both of these teaching hospitals are under the Ministry of Higher Education, Malaysia (Ministry of Higher Education Malaysia, 2011).

These centers were selected as both are tertiary medical centers located at the city center of Kuala Lumpur. UMMC is located in *Lembah Pantai* (Pantai Valley) which is at the south-western part of Kuala Lumpur meanwhile; UKMMC is located in Cheras which is the south-eastern part of Kuala Lumpur. The patients were similar in terms of characteristics and treatment received. The prostate cancer patients who were followed up at UMMC were chosen as the intervention group and patients at UKMMC as the comparison group.

Both medical centres are located in Kuala Lumpur. The distance between these centres are around 10 kilometers. Patients from UMMC mostly came from the western area of Kuala Lumpur, *Petaling Jaya*, *Subang Jaya* and *Klang*. Meanwhile patients from UKMMC mostly came from the south-east and east area in Kuala Lumpur, *Sungai Besi* and *Kajang*. Since both of medical centres were far from each other. It can reduce the contamination effect of the patients in both centres.

3.2.1 University of Malaya Medical Centre (UMMC)

The University Malaya Medical Centre (UMMC) or *Pusat Perubatan Universiti Malaya* (PPUM) (formerly known as University Hospital) is the first teaching hospital under the Ministry of Higher Education (University of Malaya Medical Centre, 2010). It was established in 1968 as a tertiary care, and an educational centre for medicine, nursing and allied health sciences and applied medical research. It is a hospital located in an urban community.

The main objectives of UMMC are to provide health services, teaching and research in the field of medicine. It pioneered cardiac surgery, dialysis, intensive care, conjoined twin surgery, paediatric bone marrow transplantation and nutritional support therapy. It also gives an opportunity for basic and clinical research in postgraduate degree programme for the students to attain the highest quality in healthcare and education. The center is staffed by more than 500 medical specialists and 1,450 nurses (University of Malaya Medical Centre, 2010).

3.2.2 Universiti Kebangsaan Malaysia Medical Centre (UKMMC)

The Faculty of Medicine, *Universiti Kebangsaan Malaysia* (UKM) (or National University of Malaysia) was established on 30th May 1972 as one of the faculties in UKM (Universiti Kebangsaan Malaysia, 2010). The Hospital UKM (HUKM) was established in 1997 as a teaching hospital for students of the Faculty of Medicine, UKM, located at Bandar Tun Razak, Cheras, Kuala Lumpur. It also conduct medical and nursing training activities, medical research and clinical services (Universiti Kebangsaan Malaysia Medical Centre, 2010).

The motto of UKMMC is "Integrating Learning and Research for the Community". The mission of UKMMC is to provide quality education for health professionals and services of the highest standard based on research, evidence-based medicine, innovation and social sensitivities (Universiti Kebangsaan Malaysia Medical Centre, 2010). UKMMC is dedicated to provide excellent service and quality education and conduct research within modern, advanced and cost effective medical facilities. The vision of UKMMC is to become the leading and competitive academic medical hub staffed by knowledgeable, innovative and dedicated teams of health professionals for developing a healthy and informed society.

3.3 Study Population

3.3.1 Inclusion Criteria

i. Patients diagnosed with prostate cancer
ii. Patients not suffering from any sensory loss related to seeing and hearing
iii. Patients aged 50 years old and above
iv. Patients with ability to communicate

v. Patients having a compact disc (CD) player at home

3.3.2 Exclusion Criteria

i. Patients diagnosed with any cancers other than prostate cancer
ii. Patients diagnosed with any psychiatric diagnosis
iii. Patients who are currently using psychiatric medication
iv. Patients who are currently receiving treatment for depression, anxiety and stress
v. Patients who had prior training or current use of relaxation therapy
vi. Patients who are enrolled in any experimental drug trial
vii. Patients who exhibit muscular or skeletal disability (eg: bed-bound) to learn Progressive Muscle Relaxation Training
viii. Patients who are not able to concentrate for one hour duration of time
ix. Patients who do not understand Malay or English languages

3.4 Sampling Method and Sample Size Estimation

3.4.1 Sampling Procedure

All prostate cancer patients on follow up treatment seen at UMMC and PPUKM between July 2010 to June 2011 and who consented and fulfilled the eligibility criteria were recruited until required number of sample size was met.

3.4.2 Sample Size Estimation

For a study comparing two means in two independent groups, the equation for sample size is used (Rosner, 2000):

$$N = \frac{2\sigma^2 (Z_\alpha + Z_\beta)^2}{\Delta^2}$$

However another option, sample size estimation also can be calculation by using statistical sample size software like OpenEpi, Epi Info6, Power and Sample Size Calculation (PS) Software etc.

As there were many outcomes measured in the study, the sample size estimation was calculated based on the each outcomes ie: depression, anxiety, stress and health related quality of life.

3.4.2.1 Depression

The estimated sample size for the perceived depression was based on the study by Hee at al., (2005) among breast cancer patients. The perceived depression means score using Multiple Affective Adjective Checklist (MAACL) for Anxiety and Depression assessment. At the end of the trial, the score of mean depression for intervention study was 7.32 (SD: 7.21) and the mean score for the perceived depression among comparison group was 21.62 (SD: 5.52). Therefore, the mean difference (δ) between experimental and control group was 14.40 points.

At a significant level of 0.05, power of 80 percent (Cohen, 1992) and the different between two groups for at least 14.40 points with standard deviation of 5, sample size required for each group was 54 using OpenEpi Sample Size calculation (Dean el al., 2013). After adjusting for attrition by 20 percent, the minimum sample size required for each group was 64.

3.4.2.2 Anxiety

The estimated sample size for the anxiety was based on the study by Bastani et al., (2005) among pregnancy women. The perceived trait anxiety means score using Spielberger's State-Trait Anxiety Inventory (STAI) assessment in the pre-intervention was 35.65 points and post-intervention was 22.71 points in the intervention group. Meanwhile, in the comparison group, the perceived trait anxiety mean score was 37.58 points in pre-intervention and 38.50 point in post-intervention. The mean difference score in the intervention group was 12.94 points and the mean difference score in the comparison group was -1.00 points. Therefore, the mean difference (δ) between experimental and control group was 13.94 points.

At a significant level of 0.05, power of 80 percent (Cohen, 1992) and the different between two groups for at least 13.94 points with standard deviation of 5, the sample size required for each group was 56 using PS sample size calculation program (Dupont & Plummer, 1990). After adjusting for attrition by 20 percent, the minimum sample size required for each group was 68.

3.4.2.3 Stress

The estimated sample size for the perceived stress was also based on the study by Bastani et al., (2005) among pregnancy women. The perceived stress mean score using Cohen Perceived Stress Scale (PSS) assessment in the pre-intervention was 31.29 points and post-intervention was 24.44 points in the intervention group. Meanwhile, in the comparison group, the perceived stress mean score was 30.98 points in pre-intervention and 37.98 point in post-intervention. The mean difference

score in the intervention group was 6.85 points and the mean difference score in the comparison group was -6.54 points. Therefore, the mean difference (δ) between experimental and control group was 13.39 points.

At a significant level of 0.05, power of 80 percent (Cohen, 1992) and the different between two groups of at least 13.39 points with standard deviation of 5, sample size required for each group was 58 using PS sample size calculation program (Dupont & Plummer, 1990). After adjusting for attrition by 20 percent, the minimum sample size required for each group was 70.

3.4.2.4 Health Related Quality of Life

The estimated sample size for the health related quality of life was based on the study by Ghafari et al., (2009) among multiple sclerosis patients. The health related quality of life means score using SF-8 assessment in the pre-intervention was 42.07 points and post-intervention was 29.64 points in the intervention group. Meanwhile, in the comparison group, the perceived trait anxiety mean score was 29.16 points in pre-intervention and 26.95 point in post-intervention. The mean difference score in the intervention group was 12.43 points and the mean difference score in the comparison group was -2.21 points. Therefore, the mean difference (δ) between experimental and control group was 14.64 points.

At a significant level of 0.05, power of 80 percent (Cohen, 1992) and the different between two groups of at least 14.64 points with standard deviation of 5, sample size required for each group was 53 using PS sample size calculation program (Dupont & Plummer, 1990). After adjusting for attrition by 20 percent, the minimum sample size required for each group was 63.

Overall the sample size ranged from 63 to 70 in one group.

3.5 Recruitment of Patients

Screening of the patients was carried out at the Urology Clinic in both centres. Eligible patients were identified through hospital record reviews and face to face interview. They were informed about the study and its objectives. The participants were recruited by the principal investigator. The patient's information sheet containing the brief information about the study and the procedure were given to the patients. Inform consent was obtained from the patients before starting data collection.

3.6 Flowchart of the Study

The flowchart of the methodology shown in Figure 3.1

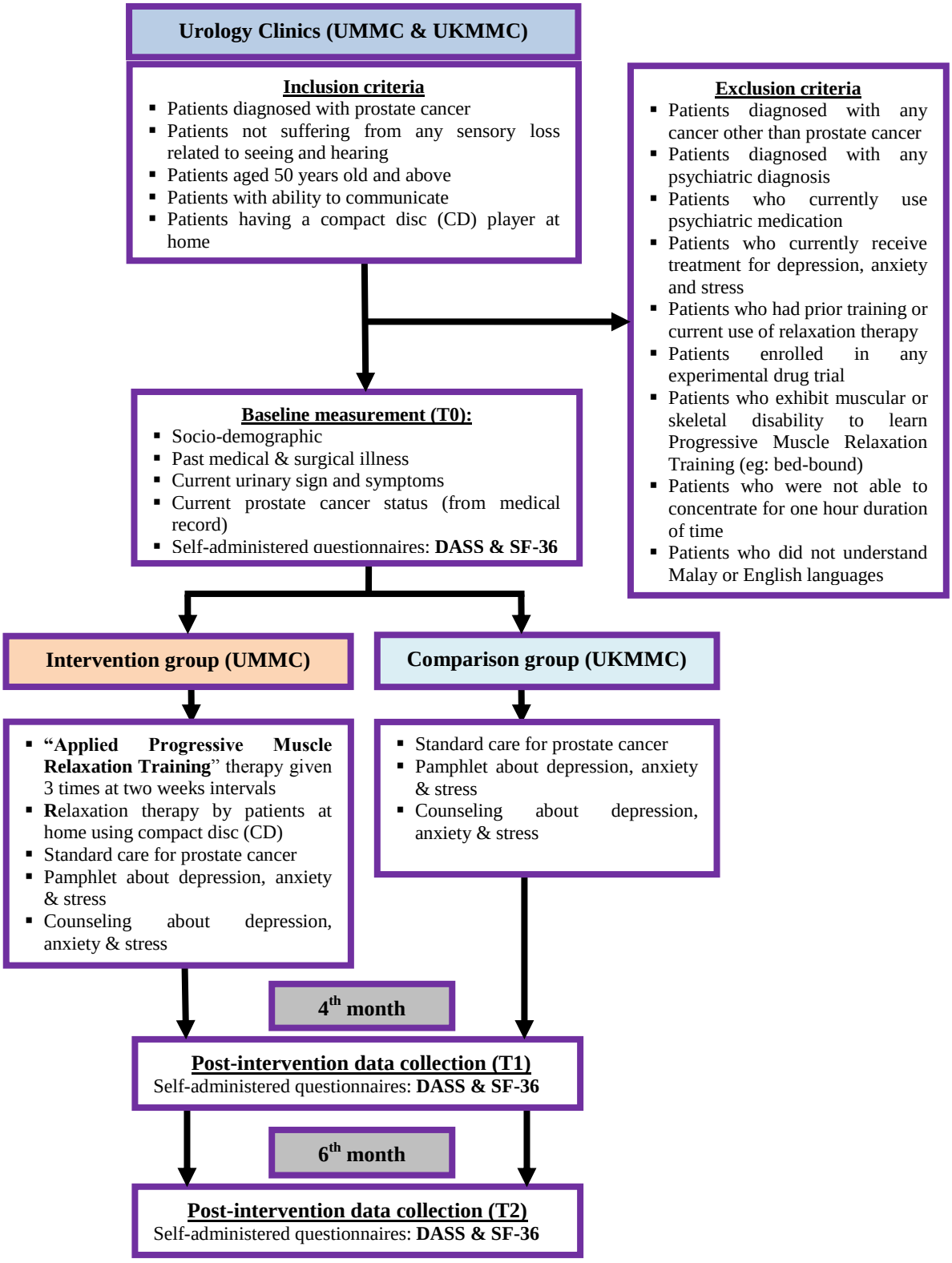


Figure 3.1: Flowchart of the study

3.7 Intervention

3.7.1 The Applied Progressive Muscle Relaxation Training (APMRT)

The intervention implemented was "Applied Progressive muscle Relaxation Training" (APMRT). The therapy consisted of three sessions of APMRT which was carried out at two weeks interval. Each session contained six modules. It was conducted by the principal investigator (PI) and/or one occupational therapist (OT). The occupational therapist is a senior occupational therapist with twelve years working experience. She is holding a degree in occupational therapy and mostly she covers any referral for cardiac rehabilitation specifically on applied progressive muscle relaxation training in UMMC.

The therapy was given at the rehabilitation clinic, UMMC or at the patients' home if they were not able to come to the hospital. The standard care for prostate cancer was still given to the patients. It was conducted by the urologist or oncologist depending on staging of the prostate cancer.

3.7.2 Modules and Mode of Delivery

There were six modules in the APMRT and all the modules were carried out for approximately two hours. The details of the modules are as follows:

3.7.2.1 First Module

The first module of the training was an introductory group discussion of depression, anxiety and stress-related issues and quality of life in prostate cancer, as well as a

rational and general description of the purpose of relaxation. The important information about confidentiality and commitment to the study were also explained.

Each patient was provided a written training manual of APMRT. Picture guides of APMRT which provide visual illustrations supplement the therapist's demonstration to make it easier for the prostate cancer patients to understand the therapy.

3.7.2.2 Second Module

The second module was focused on teaching the patients on breathing technique. It is to enhance relaxation before proceeding to the actual relaxation therapy. The patients learn diaphragmatic breathing to achieve an optimal level of arousal (Caudil, 1995). The breathing technique took almost ten minutes to get proper abdominal breathing (breathe in for five seconds and breathe out for seven seconds). It was also meant to inhale and deliver more oxygen to the muscle and tissues and improve the body's internal rhythm. However, if the patient had breathing difficulty, breathe in and breathe out were counted for four seconds only.

3.7.2.2.1 Abdominal Breathing Technique

There were four steps on how to do abdominal breathing technique:

The first step was to place one hand on the chest and the other hand on the abdomen. While taking a deep breath, the hand on the abdomen should rise higher than the one on the chest. This was to ensure that the diaphragm was pulling into the bases of the lungs.

The second step was to breathe in through the nose slowly by imagining that they were sucking in all the air in the room. It was held for a count of five seconds (or as long as the patients could but not exceeding seven seconds).

The third step was to breathe in and breathe out through the mouth for a count of seven seconds. The air released with relaxation gently contracts the abdominal muscles to go quickly and evacuate the remaining air from the lungs. Deepening the respirations is achieved by breathing out and not by inhaling more air.

For the final step, the patients had to repeat the cycle for four more times, for five deep breaths and they had to try to breathe at a rate of one breath every ten seconds (or six breaths per minutes). At this rate the heart rate variability increased and had a positive effect on cardiac health.

Once the patients felt comfortable with the technique, they were asked to incorporate words that could enhance the exercise. They were encouraged to say to themselves the word, relaxation (with inhalation) and stress or anger (with exhalation). It was to bring in the feeling the patients want with inhalation and release those the patients do not want by exhalation.

3.7.2.2.2 Abdominal Breathing Instruction

The patients in turn demonstrated the abdominal breathing by following the instructor's voice. The script used for the abdominal breathing technique intervention is shown in Appendix A.

3.7.2.3 Third Module

The third module was related to relaxation with the help of a shortened version of Jacobson's progressive muscle relaxation (tense for five seconds and relax for ten seconds) on the sixteen large muscles. The sixteen large muscle groups were the right hand and forearm, right biceps, left hand and forearm, left biceps, upper section of cheeks and nose, lower section of cheeks and nose, neck and throat. Then, it continues to the chest, shoulders and upper part of back, abdominal region and stomach, right thigh, right calf, right foot, left thigh, left calf and left foot involved in the relaxation.

This module took around twenty to thirty minutes to complete. The patients in turn demonstrated the relaxation technique by following the instructor's voice. The instruction used for the Applied Progressive Muscle Relaxation Training for intervention is shown in Appendix B.

3.7.2.4 Fourth Module

The fourth module was related to end of the relaxation therapy. This module took around five minutes to complete. The patients in turn demonstrated the end of relaxation session by following the instructor's voice. The script used for the end of the relaxation therapy intervention is shown in Appendix C.

3.7.2.5 Fifth Module

The fifth module is a repetition of the second, third and fourth modules. It included the breathing technique, the APMRT and the end of the relaxation therapy. The

patients in turn demonstrated the relaxation technique by using the compact disc (CD) instruction with the instructor's voice. The volume of the instructions played to the intervention group was set between 40 – 50 decibels, which was an acceptable sound level. All these modules took around sixty minutes to complete.

3.7.2.6 Sixth (Final) Module

The final module concludes all the relaxation training sessions. A brief discussion with the patients concerning their feelings about the session and any problems that they may have experienced in following the instructions were discussed. They confirmed that they have mastered the technique.

3.7.2.7 Mode of Delivery

During the relaxation training, the patients were seated in a quiet room and were asked to follow the different exercises demonstrated by the investigator. Each patient was covered with a comfortable blanket and the room lights were dimmed. The temperature of the intervention room was around 25 degree Celsius. The patients were refrained from smoking, strenuous physical exercise, eating and consuming caffeine for at least one hour prior to therapy.

3.7.3 Daily Home APMRT by Patients

The patients were advised to practice the applied relaxation twice daily throughout the study period (for example during the morning session after having morning activities and before going to sleep at night). They were given a compact disc (CD) containing instructions for systematic tensing and relaxation of specific muscle

groups. It started with the muscle group in the upper body and progresses down to the muscle group of the lower part of the body, guidance provided by the instructor's voice. The CD was provided by the Department of Psychological Medicine, Faculty of Medicine, University of Malaya. The script was used for the systematic tensing and relaxation of muscle groups. It was also given to the patients for them to practice at home for more effective training.

3.7.4 Pamphlets and Health Information

The investigator used a poster and pamphlets to provide a more effective programme to the patients. The pamphlets contain the topics relevant to prostate cancer, general information on depression, anxiety and stress as well as quality of life in prostate cancer. The pamphlets were given to the patients for them to read at home.

The question and answer (Q&A) session was also carried out during the interview. The patients were free to ask any information about prostate cancer and psychological problems which they were not clear about. The discussion was facilitated by the investigator. However, any questions that involved prostate cancer treatment, the patients were advised to discuss with the urologist or oncologist.

3.7.5 Monitoring of Compliance

To increase the compliance, the patients were monitored using worksheet marking and phone calls.

3.7.5.1 Worksheet

The patients were encouraged to record the frequency of home relaxation practice in a log sheet provided during the study period (Appendix D). The log sheet was designed in a calendar format. The patients were instructed to put a mark on the particular date and time in the log sheet when they had practised the therapy. In addition, they were asked to mark their relaxation level before and after relaxation therapy at home. The rates of the relaxation level ranged from 0 (very relaxed) to 10 (very tense). The patients were encouraged to provide honest responses on the relaxation home work.

3.7.5.2 Phone Calls

The principal investigator initiated telephone calls to monitor the patients' compliance and encourage the patients to practise at home. It was also to remind the patients to record their therapy in the worksheet given to them. The patients were contacted by phone every two weeks. They were free to talk about any problems that arise and their feelings towards the therapy.

3.8 Comparison Group

Prostate cancer patients from UKMMC were selected as the comparison group. The comparison group in the quasi-experimental trial was not given any relaxation therapy. However, it was unethical to withhold information which could benefit the subjects.

The pamphlets and health information given to the intervention group were also given to the comparison group. The content in the pamphlet and health information was similar.

A general discussion about their concerns related to their health and nursing care was also given. The question and answer (Q&A) sessions were conducted during the interview. Like in the intervention group, the patients could freely ask any information about prostate cancer and psychological problem which were not clear. The discussion was facilitated by the investigator. However, any questions that involved prostate cancer treatment, they were advised to discuss with the urologist or oncologist.

The standard care for prostate cancer was still given to the patients by the urologist or oncologist depending on the stage of their prostate cancer. Telephone calls for this group were also made biweekly throughout the six months study period to avoid loss of follow up. The phone contacts were initiated by the principal investigator of the study and they were also free to talk about any arising problems.

3.9 Assessments of Health Related Quality of Life and Self-perceived Depression, Anxiety and Stress

At 4-months after the first therapy, the patients from the intervention group were asked to complete an assessment defined as post-test 1 (T1). After T1, they were asked to do the relaxation therapy on their own by using the CD containing the relaxation script and the text of relaxation therapy given to them. At 6-months after the first therapy, the patients were asked again to complete an assessment defined as post-test 2 (T2).

For the comparison group, the patients were asked to complete the assessment at 4-months (T1) and 6-months (T2) similar as the intervention group. The assessment for the comparison group was taken after they had a rest for one hour. This is to ensure that the patients from the comparison group relax naturally before the administration of questionnaire. They were advised not to do any heavy activity one hour before the one hour rest period.

There were six measurements used to evaluate the therapy given. There were: (i) self-perceived depression; (ii) self-perceived anxiety; (iii) self-perceived stress; and (iv) general health related quality of life (HRQOL) assessment. The measurement of general HRQOL contained three components which were: (i) Physical component summary (PCS); (ii) Mental component summary (MCS); and (iii) total quality of life (QOL). The following outcome of measurements monitored are shown in Table 3.1

Table 3.1: Measurements taken during the study period

	Measurement for intervention and control groups	**Intervals taken**
1.	Self-perceived Depression	Baseline, 4 months, 6 months
2.	Self-perceived Anxiety	Baseline, 4 months, 6 months
3.	Self-perceived Stress	Baseline, 4 months, 6 months
4.	Health related quality of life (HRQOL)	
	i. Physical component summary	Baseline, 4 months, 6 months
	ii. Mental component summary	Baseline, 4 months, 6 months
	iii. Total quality of life (QOL)	Baseline, 4 months, 6 months

3.10 Method of Data Collection

Data was collected through face to face interview, self-administered questionnaire, review of medical record and review of log book.

3.10.1 Face to Face Interview

Baseline information was collected by face to face interview. The baseline information included the socio-demographic data such as age, ethnicity, religion, marital status, number of children, living condition, educational level, working status, smoking status, drinking status, sexual activity status and drug history. The information about past medical and surgical history including history besides prostate cancer, family history of prostate cancer, family history of other cancer and current medication were also taken by using this method.

Lastly, the information about the urinary complaints such as frequency, urgency, nocturia, intermittency, straining, dysuria, haematuria and incomplete emptying were also taken by using this method. The patients were also asked about satisfaction of their micturition. This information was self-reported by the patients (Appendix E). The investigator could clarify the questions and the inconsistent answers from the patient in order to reduce information bias.

3.10.2 Review of Medical Records

Patients' medical records were reviewed to counter check the information given by the patients and to obtain other data on the medical and surgical illness, drug histories and cancer status of the patients.

The cancer status included life in prostate cancer, PSA level during diagnosis and latest PSA level, histology result during biopsy, Gleason score and radiological reports for metastases status. The current treatment and family history of prostate cancer were also taken.

3.10.3 Review of Log Book

The frequency of home practice of APMRT was taken from the log book. The self-report from the patients for their home practice were calculated.

3.10.4 Self-Administered Questionnaires

Outcome measurements such as depression, anxiety and stress as well as health related quality of life were collected using self-administered questionnaires. The outcome measures of depression, anxiety and stress were assessed using Depression Anxiety Stress Scales Version 21 (DASS-21) (Appendix F) and the health related quality of life was assessed using Short Form Health Survey the RAND-36 General Health Related Quality of Life (SF-36) (Appendix G).

3.10.4.1 Depression Anxiety Stress Scales Version 21 (DASS-21)

The psychological self-reported depression, anxiety and stress were assessed using self-administrated Depression Anxiety Stress Scale Version 21 (DASS-21) questionnaire (Lovibond & Lovibond, 1995a) (Appendix F). DASS-21 comprises twenty one items that are divided into three subscales that measure depression, anxiety and stress (Appendix F). There are seven items for depression (DASS-

Depression), seven items for anxiety (DASS-Anxiety) and seven items for stress (DASS-Stress). The depression sub-scale assesses the dysphoria, hopelessness, devaluation of life, self-deprecation, adhedonia, inertia and lack of interest. The anxiety sub-scale assesses the autonomic arousal, skeletal muscle effects, situational anxiety and subjective experience of anxious affects. The stress sub-scale assesses difficulty in relaxing, nervous arousal and being easily upset or agitated, irritable or over-react and impatient (Lovibond & Lovibond, 1995a).

The original DASS-Depression, DASS-Anxiety and DASS-Stress subscales have Cronbach's alpha ranged from 0.76 to 0.84, while the internal consistency ranging from 0.83 to 0.91. (Lovibond & Lovibond, 1995a). The DASS has been translated into various languages (Akin & Çetin, 2007; Apóstolo, Mendes, & Azeredo, 2006; Bados, Solanas, & Andrés, 2005; Musa, Salmiah, & Nurul Ain, 2009). The Malay languange of DASS-21 was translated by Musa et al., (2007) and had demonstrated a good concurrent and criterion-related validity with Cronbach's α of 0.84, 0.74 and 0.79 respectively. DASS-21 can be used to measure the dimension of depression, anxiety and stress among clinical sample (Brown, Chorpita, Korotitsch, & Barlow, 1997; Gloster et al., 2008; Musa et al., 2009) and non-clinical sample (Henry & Crawford, 2005)**.**

In this study, the English and Malay language versions of DASS-21 were used. The patients were asked to rank on 4-point Likert scales to rate the extent to which they had experienced each statement over the past four weeks. The scales were: 0 = did not apply to me at all, 1 = applied to me to some degree or some of the time, 2 = applied to me a considerable degree, or good part of the time, and 3 = applied to me very much or most of the time (Lovibond & Lovibond, 1995a). The score for depression,

anxiety and stress were calculated by summing the score for the relevant items and multiply by two to get the final scores for the relevant items and converting these into percentile scores. The higher scores indicated greater depression, anxiety and stress levels.

The classification for the depression, anxiety and stress scores is shown in Table 3.2. The cut-off score was suggested by Lovibond & Lovibond (1995a).

Table 3.2: General guideline for the DASS severity ratings

Severity	Z score	Percentile	DASS-Depression	DASS-Anxiety	DASS-Stress
Normal	< 0.5	0 – 78[a]	0 – 9	0 – 7	0 – 14
Mild	0.5 – 1.0	78 – 87	10 – 13	8 – 9	15 – 18
Moderate	1.0 – 2.0	87 – 95	14 – 20	10 – 14	19 – 25
Severe	2.0 – 3.0	95 – 98	21 – 27	15 – 19	26 – 33
Extremely Severe	≥ 3.0	98 – 100	≥ 28	≥ 20	≥ 34

[a] : percentile cut-offs corresponding to each DASS category

Based on the cut-off percentiles, a score less than 78th percentile was considered normal. Meanwhile, score from 78th to 87th percentiles are labeled as mild; 87th to 95th percentiles as moderate; 95th to 98th percentiles as severe; and 98th to 100th percentiles as extremely severe (Lovibond & Lovibond, 1995a)**.** Then, the raw scores for each subscale are summed and converted into *Z* scores. Based on the *Z* scores, scoring less than 0.5 is considered normal. Meanwhile, 0.5 to 1.0: mild depression, anxiety or stress; 1.0 to 2.0: moderate depression, anxiety or stress; 2.0–3.0: severe depression, anxiety or stress; and more than 3.0: extremely severe depression, anxiety or stress (Lovibond & Lovibond, 1995a). However, most investigators used the

original score in classifying the severity of self-perceived depression, anxiety and stress.

3.10.4.2 Short Form Health Survey the RAND-36 General Health Related Quality of Life (SF-36)

The general health related quality of life (HRQOL) was assessed using Short Form Health Survey SF-36 (Hays & Morales, 2001) (Appendix G). SF-36 is a generic measure of health status as opposed to one that targets a specific age, disease or treatment (Ware, Barbara, & for the IQOLA Project, 1998) and it is a practical and valid instrument for use on older people (Walters, Munro, & Brazier, 2001).

The SF-36 comprises 36 items covering eight domains targeting Physical Component Summary (PCS) and Mental Component Summary (MCS) (Hays & Morales, 2001). These items are suitable for measuring the impact of the intervention on HRQOL (Ware et al., 1998; Ware & Sherbourne, 1992). The eight domains are: physical function (PF) (ten items), role-physical (RP) (four items), bodily pain (BP) (two items), mental health (MH) (five items), role-emotional (RE) (three items), vitality-energy (VT) (four items), general health perception (GH) (five items) and social functioning (SF) (two items). In addition, SF-36 contains a single item that provides an indication of perceived change (health transition) in general health status over one year period. Each of the eight scales scores from 0 to 100 with higher scores indicating higher function (Hays & Morales, 2001; Ware et al., 1998; Ware, Kosinski, & Dewey, 2000).

The SF-36 has been shown to be reliable and valid (Ware et al., 1998; Ware , Snow, Kosinski, & Gandek, 1993). The PCS and MCS measures demonstrated acceptable

internal consistency and test-retest reliability from data collected in the Medical Outcome Study (Ware, Kosinski, & Keller, 1994). The internal consistency for the PCS and MCS measures ranged from 0.89 to 0.94 and 0.84 to 0.91 respectively (Ware et al., 1998). The 95% confidence intervals for the eight scales are much wider compared to the two summary measures (± 13-22 points versus ± 6-7 points) (Ware et al., 1998). The SF-36 English languange was translated to Malay languange by a group of researchers from University of Science, Malaysia (USM) under the International Quality of Life Assessment (IQOLA) Project in 1998 (Bullinger et al., 1998; Ware et al., 1998). Most of the subscales of SF-36 were sensitive for the Malaysian general population except for role physical (RP) and role emotional (RE) (Abu Bakar et al., 2003).

The PCS and MCS were derived from the eight subscales. The physical function, role physical and bodily pains were strongly correlated to PCS while mental health, role emotional and social functions were strongly correlated with MCS (Ware et al., 1998; Ware & Mark, 2001). Vitality and general health correlated significantly with both summaries. A diagrammatic representation of the conceptual framework for SF-36 is shown in Figure 3.2 (Ware et al., 1998).

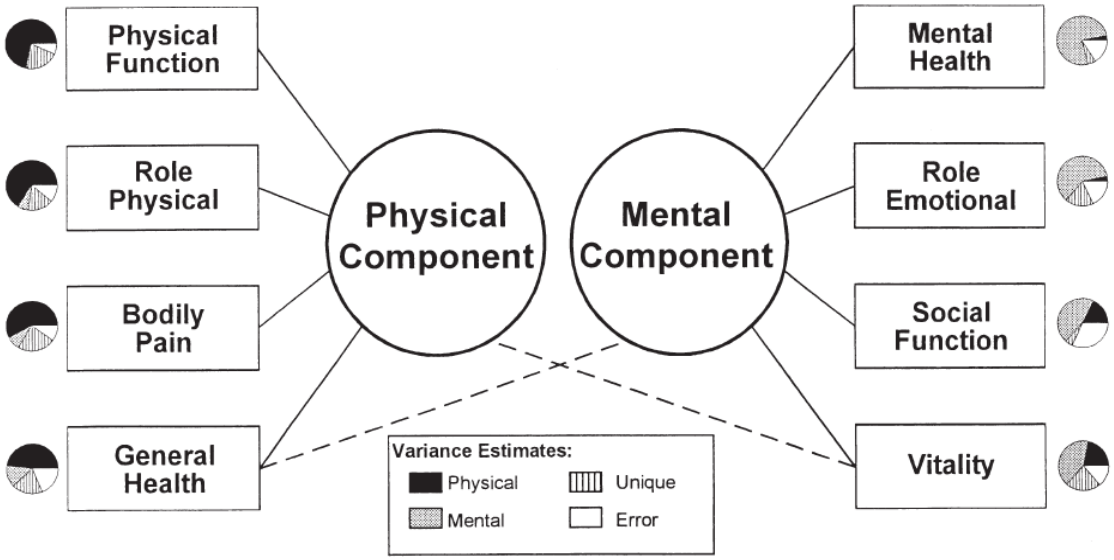


Figure 3.2: Eight domains of SF-36 with its two summaries component (Ware et al., 1998)

The questionnaires for all domains in SF-36 are mixed and not grouped to their appropriate domain. Table 3.3 shows the items, which cover each domain in the SF-36 questionnaire.

Table 3.3: Grouping of items according to domains

Domains	Items number in the questionnaire
Physical Functioning	3a + 3b + 3c + 3d + 3e + 3f + 3g + 3h + 3i
Role Physical	4a + 4b + 4c + 4d
Bodily Pain	7 + 8
General Health	1 + 11a + 11b + 11c + 11d
Vitality	9a + 9e + 9g + 9i
Social Functioning	6 + 10
Role-Emotional	5a + 5b + 5c
Mental Health	9b + 9c + 9d + 9f + 9h

SF-36 also evaluates the health transition item of the respondent for the past one year (item number two). It is useful in estimating average change in health status during the year prior to its administration. It has five levels from “much better than one year ago” to “much worse than one year ago”. However, the health transition was not calculated in scoring the scales or summary measures (Ware et al., 1998).

3.10.4.2.1 Interpretation of SF-36 Domains and the Two Health Summaries

In general, the higher the score, the better the quality of life (Ware et al., 1993). For eight domains, the score ranges from 0 to 100; where 0 is defined as very low and 100 is defined as the optimal quality of life. Meanwhile, for PCS and MCS, after their transformation and standardization, the score; (i) 0 to 49 is defined as below the average; (ii) 50 is defined as the average score; and (iii) 51 to 100 is defined as above the average (Ware, 2000). Table 3.4 shows a summary interpretation of the scores for each domain and Table 3.5 shows a summary interpretation of the scores for two summary components.

Table 3.4: Summary of information about SF-36 domains (Ware et al., 1998)

Scales	No. of item	Definition	
		Lowest score	Highest score
Physical Functioning (PF)	10	Very limited in performing all physical activities including bathing or dressing (0.8 percent)	Performs all types of physical activities including the most vigorous without limitations due to health (38.8 percent)
Role-Physical (RP)	4	Problems with work or other daily activities as a result of physical health (10.3 percent)	No problems with work or other daily activities (70.9 percent)
Bodily Pain (BP)	2	Very severe and extremely limiting pain (0.6 percent)	No pain or limitations due to pain (31.9 percent)
General Health (GH)	5	Evaluates personal health as poor and believes it likely to get worse (0.0 percent)	Evaluates personal health as excellent (7.4 percent)
Vitality (VT)	4	Feels tired and worn out all the time (0.5 percent)	Feels full of pep and energy all the time (1.5 percent)
Social Functioning (SF)	2	Extreme and frequent interference with normal social activities due to physical and emotional problems (0.6 percent)	Performs normal social activities without interference due to physical or emotional problems (52.3 percent)
Role-Emotional (RE)	3	Problems with work or other daily activities as a result of emotional problems (9.6 percent)	No problems with work or other daily activities (71.0 percent)
Mental Health (MH)	5	Feelings of nervousness and depression all the time (9.6 percent)	Feels peaceful, happy, and calm all the time (0.2 percent)

Table 3.5: Summary of information about components summary measures (Ware et al., 1998)

Scales	No. of item	Definition	
		Lowest score	**Highest score**
Physical Component Summary (PCS)	10	Limitations in self-care, physical, social, and role activities, severe bodily pain, frequent tiredness, health rated "poor" (0.0 percent)	No physical limitations, disabilities, or decrements in wellbeing, high energy level, and health rated "excellent" (0.0 percent)
Mental Component Summary (MCS)	4	Frequent psychological distress, social and role disability due to emotional problems, health rated "poor (0.0 percent)	Frequent positive effect, absence of psychological distress and limitations in usual social/role activities due to emotional problems, health rated "excellent" (0.0 percent)

The mental health scale is useful in screening for psychiatric disorder (Ware et al., 1994). The SF-36 is generally considered to the the "gold standard" for assessing general HRQOL. By using a cut-off score of 42, the MCS has a sensitivity of 74 percent and a specificity of 81 percent in diagnosing patients with depressive disorder (Berwick et al., 1991; Ware et al., 1994).

Physical functioning (PF) is the best measurement of physical assessment meanwhile and mental health (MH) is the most valid measurement of mental assessment. However, mental health is the poorest measurement of the physical component (PCS) and physical functioning is the poorest measurement of the mental component (MCS) (Ware et al., 1998).

For health transition, those who evaluate their health as "much better" improved an average of 13.2 points and those who evaluate their health as "somewhat better" improved an average of 5.8 point. The average decline of -10.8 points was observed for those who reported their health was "somewhat worse" and the average decline of -34.4 points was observed for those reporting "much worse". The changing score average of 1.6 points was for those who choose "about the same" (Ware et al., 1998).

3.10.4.2.2 Scoring of SF-Domains

Each domain in SF-36 was scored and calculated separately. In the questionnaire form, the pre-coded values of each response were given. However, the score for each question were not obtained by adding up all the values. In the guidebook by Ware et al., (1998), the final values of each item as according to their responses are used in

the scoring of each domain. Appendix H lists the corresponding final values for each pre-coded items.

The final score of each domain were summed for all items according to the final values. For example for Role-Physical (RP) domain, the final raw score can range from 2 to 8 and for the Physical Functioning (PF) domain; the final raw score can range from 10 to 30. The conversion of the pre-coded values to the final values is done to all the items in each domain. The score in each domain is then the sum of all final values of the items in that particular domain.

3.10.4.2.3 Calculation of SF-36 Domains

SF-36 score for each domain ranges from 0 to 100 with a score of 0 means the lowest HRQOL and a score 100 means the highest HRQOL for each domain. However, to get this, the score for each domain were transformed to a 0 to 100 scale using the formula below:

$$\text{Transformed Scale} = \left(\frac{\text{actual raw score} - \text{lowest possible score}}{\text{possible raw score range}} \right) \times 100$$

Table 3.6 lists the lowest and highest possible score for each domain with the corresponding values of possible raw score range. These values were needed for transforming the raw score to the 0 to 100 scale, which were used for the final score of the domains.

Table 3.6 : Formula for scoring and transforming scale

Scale	Sum Final Items	Lowest and highest possible raw score	Possible raw score range
Physical Functioning	3a + 3b + 3c + 3d + 3e + 3f + 3g + 3h + 3i	10 , 30	20
Role Physical	4a + 4b + 4c + 4d	4 , 8	4
Bodily Pain	7 + 8	2 , 12	10
General Health	1 + 11a + 11b + 11c + 11d	5 , 25	20
Vitality	9a + 9e + 9g + 9i	4 , 24	20
Social Functioning	6 + 10	2 , 10	8
Role-Emotional	5a + 5b + 5c	2 , 10	3
Mental Health	9b + 9c + 9d + 9f + 9h	5 , 30	25

The reported health transition (item number 2) is not calculated as the other items as raw score and transformed score. The guide by Ware (1993), suggested to treat item 11 as an ordinal data and present it as number of proportion of respondents for each response choices.

3.10.4.2.4 Health Summaries Calculation

There are three steps in calculating of the summary score:

i. Standardization of the eight domains of SF-36 to *Z*-score,

ii. Weighting and aggregation of the eight domains of SF-36 scales,

iii. Transformation of the aggregate scale to a T-score.

3.10.4.2.4.1 Standardization of Eight Domains of SF-36 to *Z*-score

Z-score standardization of the eight domains of the SF-36 is based on the means scores and the standard deviations values for Malaysian population (Abu Bakar et al., 2003) as shown in Table 3.7. The calculation involved transforming the scores of each domain to *Z*-score based on the formula:

$$Z\text{-score of each domain} = \frac{\text{Raw score of each domain} - \text{mean score for each domain}}{\text{Standard deviation of each domain for the population}}$$

Table 3.7: The norms used in calculating PCS and MCS for Malaysian population (Abu Bakar et al., 2003)

Population norms	PF	RP	BP	GH	VT	SF	RE	MH
Mean	85.98	82.03	69.96	66.74	66.79	83.73	79.23	74.66
SD	17.91	21.12	17.59	19.99	17.68	19.28	35.92	17.19

RF = Physical Functioning, RP = Role limitations due to physical health, BP = Bodily pain, GH = General health perception, VT = Vitality, SF = Social Functioning, RE = Role limitation due to emotional problem, MH = General Mental Health

3.10.4.2.4.2 Weighting and Aggregation of Eight Domains of SF-36 Scales

The next step was to weight and aggregate the eight domains of the SF-36. Each summary (PCS and MCS) correlated differently to each of the eight domains; therefore the two summaries were weighted according to their respective coefficient factors. In this study, the calculation of the two health component summaries were based on the Singaporean population coefficients (Thumboo et al., 2003) as no validation study has been carried out among the Malaysian population (Table 3.8).

Table 3.8: The norms used in calculating PCS and MCS (Thumboo et al., 2003)

Population norms	PF	RP	BP	GH	VT	SF	RE	MH
PCS	0.320	0.484	0.132	-0.116	-0.137	0.146	0.418	-0.151
MCS	-0.091	-0.173	0.146	0.337	0.386	0.149	-0.121	0.386

RF = Physical Functioning, RP = Role limitations due to physical health, BP = Bodily pain, GH = General health perception, VT = Vitality, SF = Social Functioning, RE = Role limitation due to emotional problem, MH = General Mental Health

Each domain is weighted with their respective coefficient factor. The total aggregate is obtained using the formula below.

Aggregate PCS = $\sum$ [z-score of each domain x respective physical factor coefficient]

Aggregate MCS = $\sum$ [z-score of each domain x respective mental factor coefficient]

Therefore, for both PCS and MCS, the final aggregate score was the total weighted score of each domains based on their respective coefficients.

3.10.4.2.4.3 Transformation of the Aggregate Scale to a T-score

The final step was to transform the aggregate score to a T-score. This transformation was based on the United States norms of the population mean of 50 and standard deviation of 10 (Ware, 2000). This transformation resulted in normally distributed scores for PCS and MCS.

T-score PCS = [Aggregate PCS score x 10] + 50

T-score MCS = [Aggregate MCS score x 10] + 50

3.11 Clinically Meaningful Difference in Assessment of Health Related Quality of Life

In any clinical trial assessing survival end-point, the quality of life instrument need a guideline on how much of the difference in the scores are clinically significant. Statistical significance tests are concerned solely with evaluating the probability that the observed patterns in the data could have arisen purely by chance. It does not necessarily indicate clinical relevance of the finding (Fayers & Machin, 2007b). Guyat et al., (1986) have suggested a 0.3 to 0.5 standard deviation is representing as clinically meaningful change.

A difference between 6.5 to 8.3 points in SF-36 scores was considered clinically significant (Jaeschke, Singer, & Guyat, 1989; Juniper, Guyatt, Willan, & Griffith, 1994; Ware et al., 1994). Meanwhile, assessment using UCLA – Prostate Cancer Index (UCLA-PCI) and Expended Prostate Cancer Index Composite (EPIC) questionnaires, a ten points difference were recommended (Litwin et al., 2001).

3.11 Study Variables

The operational definitions in this study are summarized in Table 3.9

Table 3.9: Operational definitions

Variables	Description
Age (years)	Actual age (in years) obtained by subtracting interview date from date of birth. Age categorized into four groups: Less than 60, 60-69.99, 70-79.99, 80 and more
Ethnicity	As stated by patient: Malay Chinese Indian Punjabi
Marital Status	As stated by patient: Married Not married Widow/Separated/Divorced
Living arrangement	As stated by patient: Alone With partner With family With friend
Educational Status	As stated by patient. The highest level of formal education of the respondent according to Malaysian education system No formal education Primary: Standard 1 to 6 Secondary: Form 1 to 5 Tertiary: College/University
History of chronic disease	As stated by patient and/or verified by medical records. **Hypertension** (BP ≥ 140/90 mmHg) **Hyperlipidemia** (serum cholesterol ≥ 6.2 mmol/l) **Heart disease** **Diabetes mellitus** (FBS ≥ 7.0 mmol/l or 2-hourpostprandial blood sugar ≥ 11.1 mmol/l) **Gout/joint problem**
Past surgical history	History of any major surgery as stated by patient and verified by medical records: Yes No

Table 3.9: Operational definitions (continue)

Variables	Description
Smoking status	As stated by patient : Non smoker Former smoker Current smoker (number of sticks/day)
Drinking status	As stated by patient: Non drinker Ever drinker Current drinker (+ age at start drinking)
Drug history	As stated by patient: Non drug addict Former drug addict Current drug addict
Sexual activity	As stated by patient: Active Not active
Problems with Micturition	As described by patient: **Nocturia** (excessive urination during night time) **Frequency** (Have to urinate again less than 2 hours after finished urinating) **Intermittency** (Have to stop and start again several times during micturition) **Incomplete emptying** (Sensation of still having urine in bladder not completely emptied after micturition) **Urgency** (Find difficulty to postpone urination.) **Dysuria** (Pain during urination) **Hematuria** (presence of blood in urine) **Straining** (Have to push or strain to begin urination)
Life in prostate cancer (months/years)	Date of interview minus Date of confirmation of prostate cancer from biopsy result.
Type of carcinoma	As documented in patient's medical record.
Histology/biopsy result	As documented in patient's medical record.
Presenting PSA	PSA reading before referral to urologist for prostate biopsy (as documented in patient's medical record).

Table 3.9: Operational definitions (continue)

Variables	Description
Latest PSA	Most recent PSA as documented in patient's medical record at time of interview
Metatases status	As documented in patient's medical record.
Type of treatment	As stated by patient & verified by patient's medical record. Prostatectomy Radiotherapy Prostatectomy & Radiotherapy Others

3.12 Data Management

The questionnaires were checked at the end of each interview session and before compilation to ensure the completeness of the questionnaire. For any missing data found, the patients were identified and contacted again through telephone calls. The data was entered and coded into the personal computer using a Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS Inc, Chicago, IL) (Leech, Barrett, & Morgan, 2005).

The double data entry was checked using EpiInfo 6 software by making a copy of the MDB file. The two data entry personnel then entered in both sets of data i.e. one into the original file and the other into the copy data file. The two MDB files were later compared in Data Compare for differences.

3.13 Data Analysis

The analysis was conducted using Statistical Package for Social Sciences (SPSS) Version 20.0 (IBM SPSS Software).

3.13.1. Reliability Analysis

Reliability analysis was conducted to measure the degree of consistency of a measurement. The internal consistency reliability was conducted by using Cronbach's α analysis. Technically, Cronbach's α is the square of the expected correlation with a data set of similar format having perfect reliability (Riffenburgh, 2006). The calculation of Cronbach's α is based on the number of items (i.e. the number of questions on a questionnaire) and the average inter-item correlation. When we assume that a question measures a true score, then each individual question will measure the true score plus a certain amount of random error (Hinton, Brownlow, McMurray, & Cozens, 2004).

The Cronbach's α range from 0 (for completely unreliable test) to 1 (for a completely reliable test). The cut-off points for reliability are (Hinton et al., 2004): (i) 0.90 and above shows excellent reliability; (ii) 0.70 to 0.90 shows high reliability; (iii) 0.50 and 0.70 shows moderate reliability; and (iv) 0.50 and below shows low reliability. Many reports concluded that the acceptable values of Cronbach's α, range from 0.70 to 0.95 (Bland & Altman, 1997; Nunnally & Bernstein, 1994).

A low value of Cronbach's α could be due to a low number of questions, poor inter-relatedness between items or heterogeneous construct. Meanwhile, if the Cronbach's

α is too high, it may suggest that some questions are redundant as they are testing the same item but in a different guide (Tavakol & Dennick, 2011). A maximum Cronbach's α value of 0.90 has been recommended (Streiner, 2003).

3.13.2 Descriptive Analysis

The frequency distribution, measure of central tendencies and measure of dispersion were produced. The normality of continuous data was checked using Kolmogorov-Smirnov testing and the histogram was plotted with normal curve overlay. The significant level was set at $\alpha=0.05$. If the Kolmogorov-Smirnov test has a p-value of less than 0.05, then the null hypothesis which tested for the data normality distributed was rejected.

The normally distributed continuous data were presented in the form of mean values with the corresponding standard deviations. For the non-normally distributed continuous data, it was presented in the form of median values and their corresponding inter-quartile range. The categorical data were presented in the form of absolute number and their corresponding percentages.

The scores of depression, anxiety stress and total HRQOL were entered as continuous variables. Then, the scores of depression, anxiety and stress were classified into the categories of depression, anxiety and stress (normal, mild, moderate, severe and extremely severe). The classifications for depression, anxiety and stress depend on the cut-off scores suggested by Lovibond and Lovibond (1995a). The categories of depression, anxiety and stress were re-classified into

binary outcome (Yes / No) to determine the percentages of depression, anxiety and stress. All independent variables were entered as categorical variables.

3.13.3 Homogeneity of the Study Groups

This is a quasi-experimental study. Therefore, the comparability of the variables needs to carry out to determine that the populations in both groups were similar. It was analysed using chi-square test for categorical data. However, for the continuous data, independent t-test was used for data that were normally distributed and Mann Whitney U test was used when the data was not normally distributed.

3.13.4 Analysis for the Correlation between Physical Component Summary (PCS) and Mental Component Summary (MCS) and Correlation between Age and Total Health Related Quality of Life (HRQOL)

The correlation between PCS and MCS and correlation between age and total HRQOL were analysed based on the distribution of both variables. When the distributions of both variables were normally distributed, the correlation was analysed using Pearson's correlation coefficient. However, if the distribution of one or both variables were not normally distribution, the correlation was analysed using Spearman rho's correlation coefficient.

Pearson's correlation coefficient and Spearman rho's correlation coefficient are measuring the strength and direction of the linear relationship between these two variables. The values between 0 and 0.3 (0 and -0.3) indicate a weak positive (negative) linear relationship, and the values between 0.3 and 0.7 (-0.3 and -0.7) indicate a moderate positive (negative) linear relationship. Meanwhile, the values

between 0.7 and 1.0 (-0.7 and -1.0) indicate a strong positive (negative) linear relationship (Rosner, 2000).

3.13.5 Analysis for the paired differences in the scores (depression, anxiety, stress, Physical component summary (PCS), mental component summary (MCS) and total quality of life (QOL)) at baseline to 4-month, baseline to 6-month and 4-month to 6-month

The analyses for the mean paired differences in PCS, MCS and total QOL scores at baseline to 4-months, baseline to 6-months and 4-months to 6-months were analysed using paired t-test in both groups. Meanwhile, the analyses for the median paired differences for depression, anxiety and stress scores at baseline to 4-months, baseline to 6-months and 4-months to 6-months were analysed using Wilcoxon sign rank test in both groups.

3.13.6 Analysis for the Impact of the Applied Progressive Deep Muscle Relaxation Training on the Score for Depression, Anxiety, Stress and Health Related Quality of Life (HRQOL)

In this study, an intention to treat (ITT) analysis was applied. It was based on the initial treatment assignment and not on the treatment eventually received. ITT analysis was intended to avoid various misleading aftifacts that can arise in intervention research such as non-random attrition of participants.

Handling the missing value was a problem in ITT analysis. However it was handled by numerical imputation where the last observation carried forward to replace the missing value. This is called “Last Observation Carried Forward (LOCF)”.

The mixed design repeated measure analysis of variance (ANOVA) was carried out to compare the mean response over time for the intervention and comparisons groups

(Chan, 2004; Munro, 2001). The rationale for repeated measures ANOVA is to regard time as a factor addition to treatment. We examined both for main effect (changes for whole sample over time) and for differences between treatment condition. Repeated measurements gave two "approaches" to analyse the Within-Subjects Effect which are Univariate and Multivariate where both approaches gave the same result for the Between-Subject Effect.

3.13.6.1 Univariate Approach

The Univariate approach was tested using Mauchly's test of sphericity. It needed the Within-Subjects variance-covariance to have Type H structure (or circular in form – correlation between any two levels of Within-Subjects factor has the same constant value) (Chan, 2004; Munro, 2001). If the p-value was more than 0.05, the assumption of sphericity was valid. However, if the p-value was less than 0.05, the adjusted p-value by using Greenhouse-Geisser, Huynh-Feldt or Lower-bound was used for interpretation (Chan, 2004; Munro, 2001).

3.13.6.2 Multivariate Approach

The Multivariate approach is an assumption of correlation for each level of Within-Subjects factor is different and the vector of the dependent variables follows a multivariate normal distribution with the variance-covariance matrices being equal across the cells formed by the Between-subject effects (Chan, 2004). The homogeneity of the Between-Subjects variance-covariance was checked using Box's M test. The homogeneity was assumed when the p-value was more than 0.05.

Figure 3.3 shows the flow chart of the repeated measurement analysis for the decision. The sphericity assumption must be checked first. When the sphericity assumption was satisfied, result from univariate procedure was used. Otherwise, the adjusted or multivariate test procedure was used.

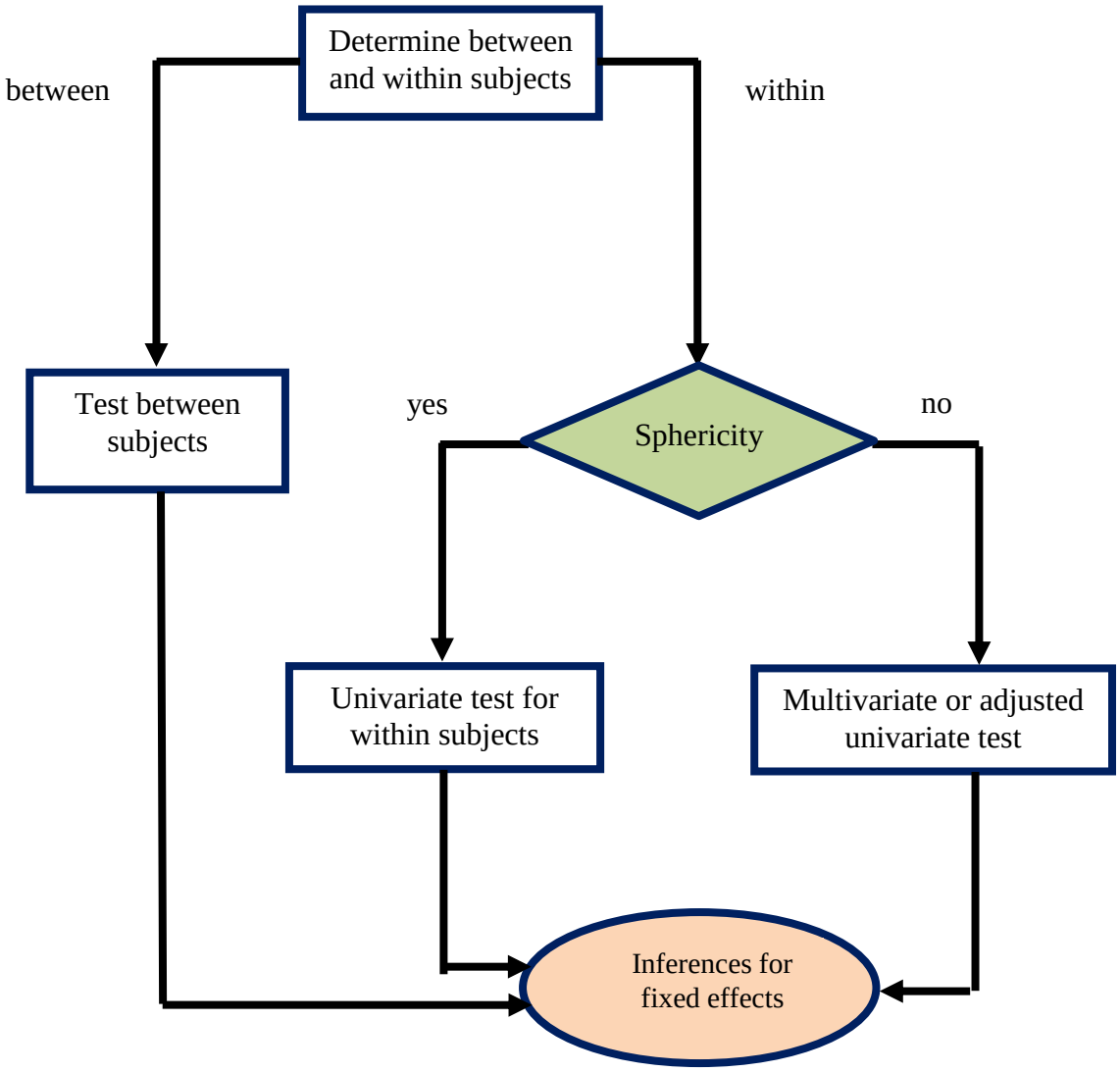


Figure 3.3: Flow Chart for Repeated Measurement Analysis (Chan, 2004)

3.13.7 Effect Size (ES)

Effect size (ES) is an indicator that measures the magnitude of an intervention effect. It is a simple measure for quantifying the difference between two groups over time on a common scale. In repeated measures ANOVA, the eta-squared (η^2) used as the correlation ratio that indicate the proportion of variance associated with or accounted for by each of the main effects, interaction and error. On average η^2 overestimates the variance explained in the population where when the sample size is larger, the amount of bias will get smaller.

However, the magnitude for each particular effect of η^2 depends to some degree on the significance and number of other effects in the design. Therefore, partial eta-squared (partial η^2) is used to minimize the issue of the effect. Partial η^2 defined as the ratio of variance accounted for by an effect and the effect plus its associated error variance within an ANOVA study. The partial η^2 computed by formula:

$$\eta^2_{\text{partial}} = \frac{SS_{\text{Effect}}}{SS_{\text{Effect}} + SS_{\text{Error for Effect}}}$$

In this study the ES was calculated using partial eta-squared (partial η^2). Cohen (1992) classified the ES as 0.2 to 0.3 as "small" effect, around 0.5 as "medium" effect and 0.8 to infinity as "large" effect.

3.13.8 Test of Within-subject Contrast

The test of within-subject contrast examines the trend displayed or the shape of the distribution of the dependent variables over levels of the within-subjects factor (i.e. time). This gave information on the best fitting model for the data.

3.14 Ethical Consideration

This research was vetted at the Department of Social & Preventive Medicine, Faculty of Medicine, University of Malaya on 9th. November 2009 and approved by the University Malaya Medical Centre (UMMC) Ethics Committee (MEC Reference number: 781.10 and amendment: 854.18) on 24th April 2010 and 25th May 2011 (Appendix I). The study was also approved by the Universiti Kebangsaan Malaysia Medical Centre (UKMMC) Ethics Committee (Project code: FF-277-2011) on 19th July 2011 (Appendix J) which governs all studies involving human by staff and students of the centre.

3.15 Consent

The patients were given a verbal and written explanation which clearly described the principles and procedures of the study. An information sheet distributed to the patients to explain the purpose and benefits of the study [Appendix K (UMMC) and Appendix L (UKMMC)]. Verbal and written consent were obtained from all participants [Appendix M (UMMC) and Appendix N (UKMMC)]. Patient confidentiality was ensured. However, if during the interview, the investigator

obtained information that required taking life saving measures, for instance suicidal behaviours; confidentiality might be compromised.

The patients were also given opportunities to ask questions and their questions were answered. The patients were informed that they could withdraw from the study and this would not affect their treatment at the respective medical centres.

3.16 Registration of Trial

The trial was registered at the Iranian Registry of Clinical Trial on 10th February 2012 (Registration ID in IRCT: IRCT201103176085N1) (Appendix O). Iranian Registry of Clinical Trials is a Primary Registry in the World Health Organization (WHO) Registry Network and abides by all the rules and regulations set by WHO. It allow the safety and efficacy of data collected for health intervention and to provide increased transparency and access to any health trials made available to the public.

3.17 Quality Metric Permission for the Scoring of Short Form Health Survey the RAND-36 General Health Related Quality of Life (SF-36)

The permission to use the SF-36 was obtained from the QualityMetric Incorporated of Lincoln, USA (License number: QM008439). It is to ensure that the investigators had the standardized administration of the SF-36 and provided updates on administration and scoring.

3.18 Budget

The budget of the study was received from the Postgraduate Research Fund (PRF), Institute of Research Management & Monitoring (IPPP), Institute Graduate Study, University of Malaya with a total amount of RM11,500 (Account number PS228/2010A).

CHAPTER 4: RESULTS

The results are presented following the sequence of the specific objectives as in section 1.10.2. This chapter is divided into eight sub-sections:

i. Reliability of SF36 and DASS-21 questionnaire.

ii. Baseline information in detail about patients' socio-demographic characteristics, history of chronic diseases, life-style practices, current urinary complaints, current cancer status and treatment for prostate cancer.

iii. Baseline scoring of self-perceived depression, anxiety and stress.

iv. Baseline scoring of the eight domains, self-reported health transition, two component summaries of health related quality of life (HRQOL) of the patients.

v. The correlation between physical component summary and mental component summary and the correlation between age and total health related quality of life (HRQOL).

vi. Process evaluation of the programme where the response rates resources and relaxation intervention sessions are described. The characteristics of respondents and non-respondents in intervention and comparison are compared. The post-intervention result at 4-month and at 6-month follow up were presented last, after the baseline information.

vii. Outcome evaluation for the impact of the applied progressive muscle relaxation on health-related quality of life, self-perceived depression, anxiety and stress and its effect sizes.

viii. Outcome evaluation of the proportions and the classification changes of self-perceived depression, anxiety and stress and self-reported health transition among study population of both the intervention and comparison groups.

4.1 Reliability of the instruments

4.1.1 Reliability for DASS-21

The internal consistency of DASS-21 was determined using Cronbach's α. Table 4.4 shows the minimum and maximum scores and the Cronbach's α of DASS-Depression, DASS-Anxiety and DASS-Stress. The values of Cronbach's alpha in all instruments were more than 0.70.

Table 4.1: Minimum Score, Maximum Score and the Cronbach's α of DASS-Depression, DASS-Anxiety and DASS-Stress

	No. of item	Minimum	Maximum	Cronbach's α
DASS-Depression	7	0	26	0.761
DASS-Anxiety	7	0	18	0.767
DASS-Stress	7	0	28	0.728

4.1. Reliability for SF-36

The internal consistency of SF-36 was determined using Cronbach's α. Table 4.4 shows the minimum and maximum scores and the Cronbach's α of SF-36. The values of Cronbach's alpha in all instruments were more than 0.70.

Table 4.2: Minimum Score, Maximum Score and the Cronbach's α of SF-36

	No. of item	Minimum	Maximum	Cronbach's α
SF-36	36	30.00	98.13	0.718

4.2 Baseline Characteristics of Patients

4.2.1 Socio-demographic Characteristics of Patients

The intervention and comparison groups were the prostate cancer patients followed up at the surgical clinics at University Malaya Medical Centre (UMMC) and Universiti Kebangsaan Malaysia Medical Centre (UKMMC) respectively. The intervention group consisted of 109 patients (age range: 55 – 90 years old) and the comparison group consisted of 84 patients (age range: 55 – 90 years old). The mean age of the intervention group was not significantly different from the comparison group.

Most of the patients were in the age group of 70 to 79.9 years old. Chinese ethnicity was the majority in both groups. Majority of the patients for both groups were married, stayed with their family members or partner and had secondary education. Both of the groups had less than 5 children (range: 1 – 11 children). Table 4.11 shows the above in more detail.

Table 4.3: Socio-demographic characteristics of patients.

		Intervention (n=109) Mean (SD)	**Comparison** (n=84) Mean (SD)	**Intervention** (n=109), Frequency (%)	**Comparison** (n=84), Frequency (%)	**p-value**
Age, years		71.77 (6.74)	73.33 (7.38)			0.127*
No. of children		4.04 (1.80)	4.42 (2.28)			0.199*
Age	Less than 60			6 (5.5)	4 (4.8)	0.277#
	60 – 69.99			34 (31.2)	20 (23.8)	
	70 – 79.99			57 (52.3)	42 (50.0)	
	80 and more			12 (11.0)	18 (21.4)	
Ethnic group	Malay			30 (27.5)	30 (35.7)	0.511#
	Chinese			61 (56.0)	40 (47.6)	
	Indian & Punjabi			18 (16.5)	14 (16.7)	
Marital status	Married			96 (88.1)	76 (90.5)	0.561##
	Not Married			4 (3.7)	1 (1.2)	
	Widow/Separate/Divorced			9 (8.2)	7 (8.3)	
Living arrangement	Alone			6 (5.5)	5 (6.0)	0.894#
	With Partner/Family			103 (94.5)	79 (94.0)	
Educational status	College/University			49 (45.0)	34 (40.5)	0.853#
	Secondary			54 (49.5)	45 (53.6)	
	Primary			6 (5.5)	5 (5.9)	

Statistical tests: * independent t-test, # chi-square test, ## Fisher's exact

4.2.2 History of Chronic Diseases of Patients

The proportion of patients having at least one co-morbidity other than prostate cancer was 89.9 percent in the intervention group and 83.3 percent in the comparison group. For both groups, hypertension was the most common co-morbidity. Hyperlipidaemia was the second and heart disease was the third common co-morbidity among intervention group, meanwhile heart disease and diabetes mellitus were the second most common co-morbidity among comparison group. A total of 63.1 percent of the patients had a history of surgery. All the above are shown in Table 4.12.

Table 4.4: History of chronic diseases and surgery of the patients*.

	Intervention (n=109), Frequency (%)	**Comparison** (n=84), Frequency (%)	**Chi-square (df)**	**p-value**
At least one co-morbidity:				
Yes	98 (89.9)	70 (83.3)	1.819 (1)	0.566
No	11 (10.1)	14 (16.7)		
Hypertension	68 (69.4)	46 (65.7)	0.253 (1)	0.615
Hyperlipidaemia	41 (41.8)	24 (34.3)	0.982 (1)	0.322
Heart disease	31 (31.6)	27 (38.6)	0.870 (1)	0.351
Diabetes mellitus	29 (29.6)	27 (38.6)	1.482 (1)	0.224
Gouty / Joint problem	20 (20.4)	8 (11.4)	2.371 (1)	0.124
Past surgical history				
Yes	74 (67.9)	49 (58.3)	2.681 (1)	0.171
No	35 (32.1)	35 (41.7)		

* The numbers and percents are showing the number of cases of having that diseases and past surgical history
df: degree of freedom
Statistical test: Chi-square test

There was an upward trend in the co-morbidity when age increased in both groups (Figure 4.1). More than half of the patients aged more than 70 years old and above had at least one co-morbidity.

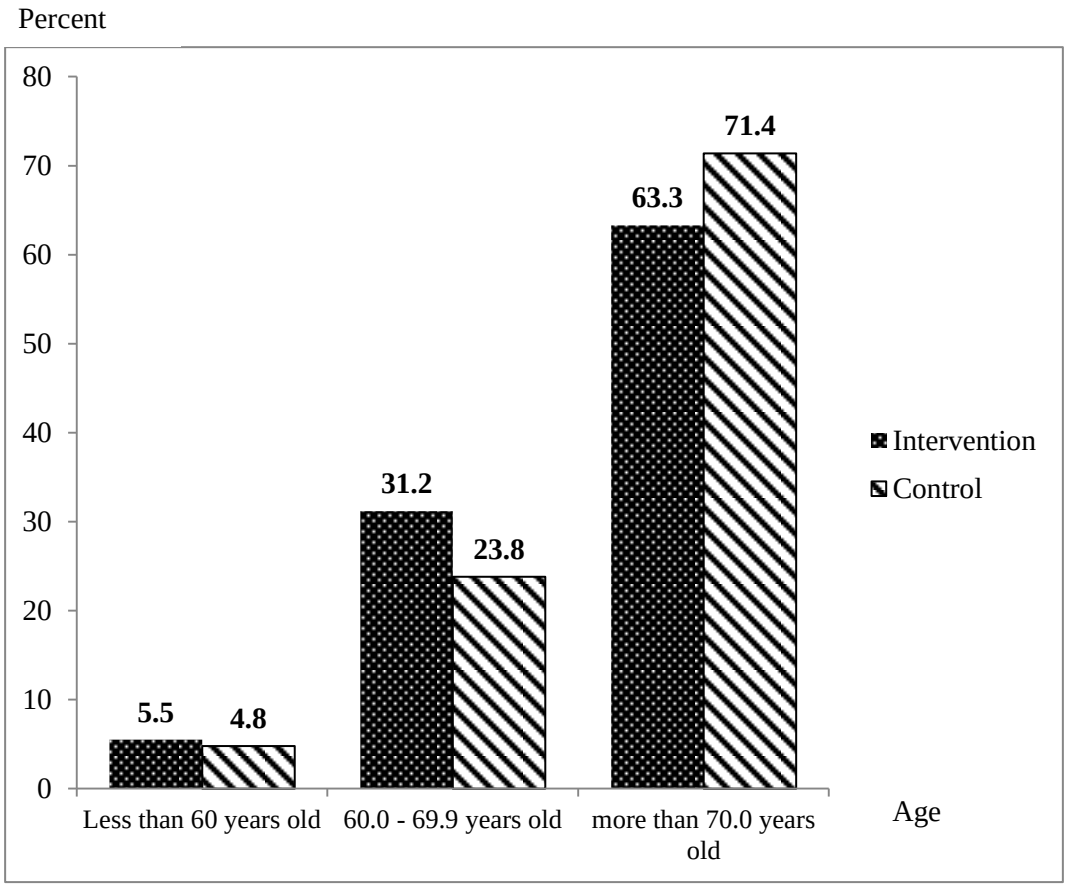


Figure 4.1: Comparison of the prevalence of at least one co-morbidities with age categories

4.2.3 Lifestyle Practices of Patients: Smoking and Alcohol Status and Sexual Activity

More than half of the patients in the intervention and comparison groups were ever smokers. Meanwhile, more than two-thirds of the patients from the intervention and comparison groups were non-drinkers. Majority of the patients were no more active

in sexual activity. There were no significant differences in lifestyle practices between the two groups (Table 4.13).

Table 4.5: Lifestyle practices of patients: Smoking and Alcohol Statuses and Sexual Activity

		Intervention (n=109), Frequency (%)	**Comparison** (n=84), Frequency (%)	Chi-square (df)	p-value
Smoking status	Non smoker	48 (44.0)	35 (41.7)	0.109 (1)	0.742
	Ever smoker	61 (56.0)	49 (58.3)		
Drinking status	Non drinker	81 (74.3)	58 (69.0)	0.652 (1)	0.419
	Ever drinker	28 (25.7)	26 (31.0)		
Sexual activity	Active	10 (9.2)	9 (10.7)	0.127 (1)	0.722
	Not active	99 (90.8)	75 (89.3)		

df: degree of freedom
Statistical test: Chi-square test

4.2.4 Current Urinary Complaints of Patients

The main current urinary complaint of patients in both groups was nocturia, followed by frequency and intermittency. The least common urinary complaints for the intervention group was hematuria (8.3 percent) and for the comparison group were dysuria and straining (10.7 percent). The details of the current urinary complaints are shown in Table 4.14.

In response to the question regarding on the satisfaction with current urination, 63.3 percent among intervention and 54.8 percent in comparison group answered positively. However this difference was not statistically significant.

Table 4.6: Current urinary complaints of patients*.

	Intervention (n=109), Frequency (%)	**Comparison** (n=84), Frequency (%)	Chi-square (df)	**p-value**
Nocturia	93 (85.3)	75 (89.3)	0.661 (1)	0.416
Frequency	65 (59.6)	56 (66.7)	1.003 (1)	0.316
Intermittency	46 (42.2)	40 (47.6)	0.564 (1)	0.453
Incomplete Emptying	39 (35.8)	33 (39.3)	0.249 (1)	0.618
Urgency	25 (22.9)	14 (16.7)	1.156 (1)	0.282
Dysuria	15 (13.8)	9 (10.7)	0.405 (1)	0.525
Hematuria	9 (8.3)	11 (13.1)	1.196 (1)	0.274
Straining	10 (9.2)	9 (10.7)	0.127 (1)	0.722

* The numbers and percent are showing the number of cases of having current urinary complaints.
df: degree of freedom
Statistical test: Chi-square test

4.2.5 Current Cancer Status of Patients

All of the patients had adenocarcinoma type of prostate cancer. More than two-thirds of the intervention and comparison groups had lived less than 5 years with prostate cancer and more than half had metastases. The mean Gleason's score in both groups was 6.52 (SD: 1.66). The Gleason's score ranged from two to 10. The mean score among comparison group [mean: 6.75 (SD: 1.60)] was higher compared to intervention group [mean: 6.40 (SD: 1.70)]. The median presenting prostatic specific

antigen (PSA) in both groups was 32.9 (IQR: 107.4) (ng/mL). The presenting PSA was ranged from 4.18 to 5100 ng/mL.

More than half of the patients had PSA less than 4 ng/mL indicating that their prostate cancer status was controlled. Only one-third or less had family history of prostate cancer (Table 4.15)

Table 4.7: Current cancer status of patients.

		Intervention (n=109) Mean (SD)/ Median (IQR)*	**Comparison** (n=84) Mean (SD)/ Median (IQR)*	**Intervention** (n=109), Frequency (%)	**Comparison** (n=84), Frequency (%)	T (df)[@] / Z[#] / chi-square (df)[&]	**p-value**
Gleason score		6.48 (1.70)	6.75 (1.60)			-1.147 (191)[@]	0.253[@]
Presenting PSA (ng/mL)		27.91 (81.94)*	41.00 (116.16)*			-1.400[#]	0.161[#]
Life in prostate cancer	Less than 5 years More than 5 years			83 (76.1) 26 (23.9)	59 (70.2) 25 (29.8)	0.852 (1)[&]	0.356[&&]
Latest PSA (ng/mL)	Less than 4 More than 4			65 (59.6) 44 (40.4)	49 (58.3) 35 (41.7)	0.033 (1)[&]	0.856[&&]
Type of carcinoma	Adenocarcinoma			109 (100.0)	84 (100.0)	-	nc
Metastases	Yes No			58 (53.2) 51 (46.8)	55 (65.5) 29 (34.5)	2.941 (1)[&]	0.086[&&]
Family history of Prostate cancer	Yes No			34 (31.2) 75 (68.8)	17 (20.2) 67 (79.8)	2.928 (1)[&]	0.087[&&]

PSA: Prostatic specific antigen; IQR: interquartile range; nc: not calculated; SD: standard deviation;
Statistical tests: [@@] independent t-test; ## Mann Whitney U test; [&&] chi-square test

4.2.6 Treatment for Prostate Cancer of Patients

Table 4.16 shows the various types of treatment given to the patients in the intervention and comparison groups. The treatment given was single or in combination. The proportion of zoladex injection was significantly higher in the comparison group while lucrine injection was significantly higher in the intervention group.

Table 4.8: Prostate cancer treatment of patients*.

	Intervention (n=109), Frequency (%)	**Comparison** (n=84), Frequency (%)	**Chi-square** (df)	**p-value**
Injection Zoladex	19 (17.4)	67 (79.8)	74.608 (1)	<0.001*
Injection Lucrine	46 (42.2)	6 (7.1)	29.624 (1)	<0.001*
Tablet Casodex	23 (21.1)	28 (33.3)	3.651 (1)	0.056
Radiotherapy	33 (30.3)	27 (32.1)	0.077 (1)	0.781
Orchidectomy	21 (19.3)	8 (9.5)	3.562 (1)	0.060
Radical Prostatectomy	14 (12.8)	7 (8.3)	0.995 (1)	0.318
Active surveillance	12 (11.0)	7 (8.3)	0.383 (1)	0.536

The number and percent are showing the number of cases of having the treatment.
df: degree of freedom
* denotes statistically significant at α=0.05
Statistical test: Chi-square test

4.3 Baseline Score

4.3.1 Health Related Quality of Life (HRQOL)

4.3.1.1 Domain of Health Related Quality of Life (HRQOL)

Table 4.17 shows the baseline mean score of the eight domains in the HRQOL. Since two domains of HRQOL were not normally distributed, the median and the inter-quartile range were presented. In both groups, the highest domain scores were mental health and the lowest domain score was role physical. All the domain scores were above 50.0. There were no significant differences in both groups in all domains.

Table 4.9: Baseline score of the domains of Health Related Quality of Life.

	Intervention (n=109) Mean (SD)	**Comparison** (n=84) Mean (SD)	**Intervention** (n=109), Median (IQR)	**Comparison** (n=84), Median (IQR)	**T (df) / Z**[#]	**p-value**
Physical Functioning	71.3 (21.4)	68.9 (22.4)			0.757 (191)	0.450[##]
Bodily Pain	68.2 (16.0)	66.3 (12.9)			0.889 (191)	0.375[##]
General Health	72.3 (16.1)	76.0 (10.1)			-1.827 (191)	0.069[##]
Vitality	68.0 (12.9)	70.5 (12.7)			-1.371 (191)	0.172[##]
Social Functioning	72.5 (18.0)	71.4 (14.6)			0.435 (191)	0.664[##]
Mental Health	81.5 (14.0)	83.8 (10.9)			-1.246 (191)	0.214[##]
Role Physical*			50.0 (100.0)	50.0 (50.0)	-0.609[#]	0.117[@]
Role Emotional*			100.0 (33.3)	100.0 (33.3)	-1.567[#]	0.542[@]

* skewed to the right;
SD: standard deviation; IQR: interquartile range
Statistical test: [##]: independent t-test, @: Mann Whitney U test

4.3.1.2 Physical and Mental Component Summaries and Total Health Related Quality of Life (HRQOL)

The interpretation of the scores for physical component summary (PCS), mental component summary (MCS) and total quality of life (QOL) were based on the scale of 0 to 100 ranges. Generally, when the score is higher, the quality of life is also higher. The overall total QOL was 70.1 (SD: 14.7). The QOL scores ranged from 29.2 to 99.4. The detail mean scores for PCS, MCS and total QOL in both groups are shown in Table 4.18.

Table 4.10: Baseline means score of Physical and Mental Component Summaries and Total Health Related Quality of Life (HRQOL).

	Intervention (n=109)	**Comparison** (n=84)	**t (df)**	**p-value**
	Mean (SD)	Mean (SD)		
Physical Component Summary (PCS)	66.7 (16.9)	67.6 (13.7)	-0.367 (191)	0.714
Mental Component Summary (MCS)	73.6 (14.8)	73.9 (10.3)	-0.144 (191)	0.886
Total Quality of Life	70.2 (16.5)	70.1 (12.1)	0.020 (191)	0.984

SD: standard deviation
Statistical test: independent t-test;

The PCS, MCS and total QOL for both intervention and comparison groups were found to be normally distributed. The scores of MCS in both groups were higher compared to PCS. However, there were no significant differences in the scores of MCS, PCS and total QOL in both groups.

4.3.1.3 Self-reported Health Transition

Self-reported health transition (item number two) in SF-36 was not included in the scoring but was used to estimate the change in health status from the year prior to the study period. As shown in Figure 4.2, majority of the patients reported that their health status was the same as the year before. Meanwhile about 20 percent of them had better health transition compared to one year ago. No patients reported that their health was much worse than a year before and no patients reported much better than one year ago in the intervention group.

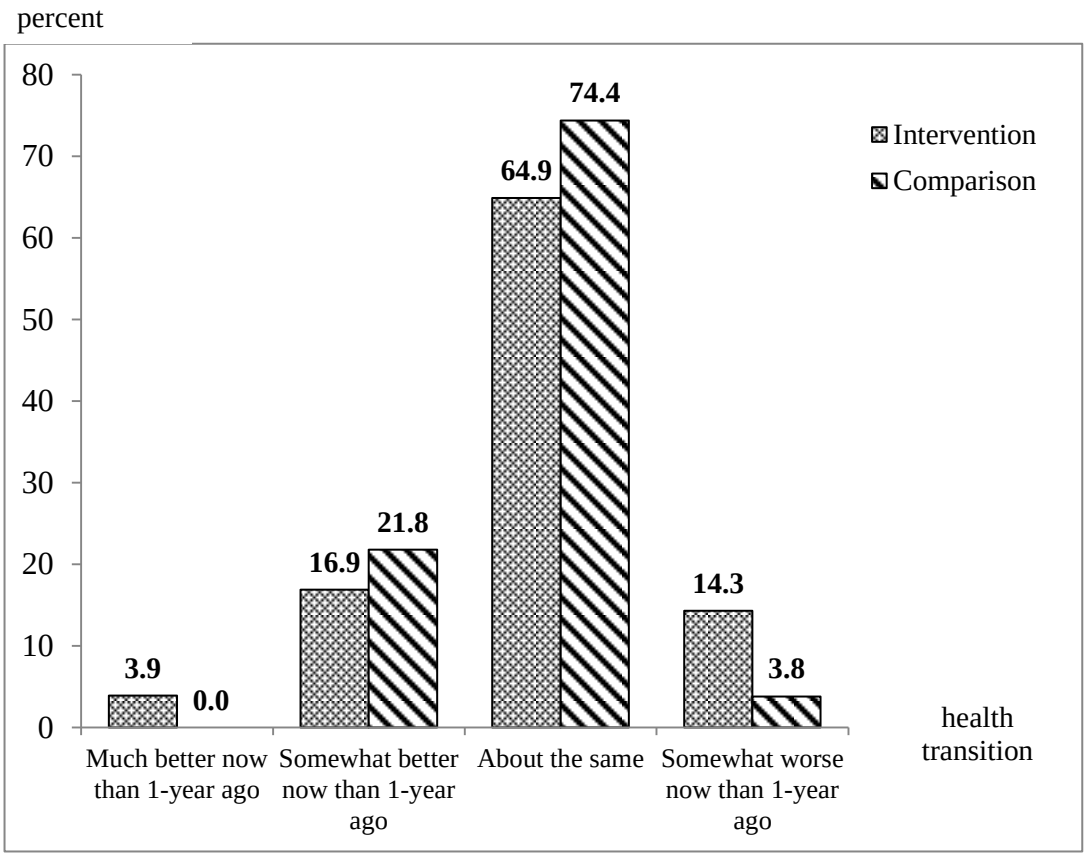


Figure 4.2: The distribution of the self-reported health transition for intervention and comparison groups

4.3.1.4 Correlation between Physical Component Summary (PCS) and Mental Component Summary (MCS)

The distributions of the Physical Component Summary (PCS) and Mental Component Summary (MCS) were found to be normally distributed. Figures 4.3(a) and 4.3(b) show the scatter plot of PCS and MCS for intervention and comparison groups respectively. The correlation between PCS and MCS for intervention group showed strong significance correlation (r=0.863, p<0.001), while the comparison group only showed moderate significance correlation (r=0.687, p<0.001).

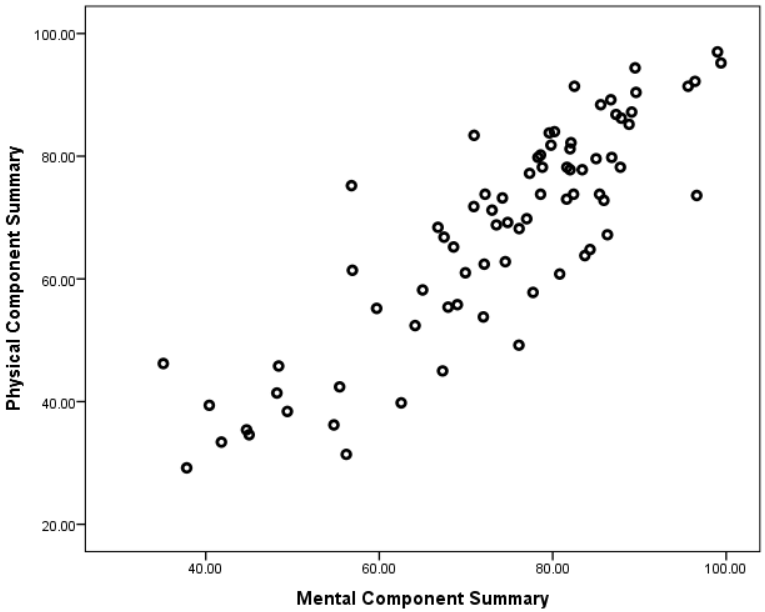


Figure 4.3(a): Correlation between PCS and MCS for intervention group.

Person's correlation coefficient (*r*): 0.863, p<0.001*

* denotes statistically significant at α=0.05

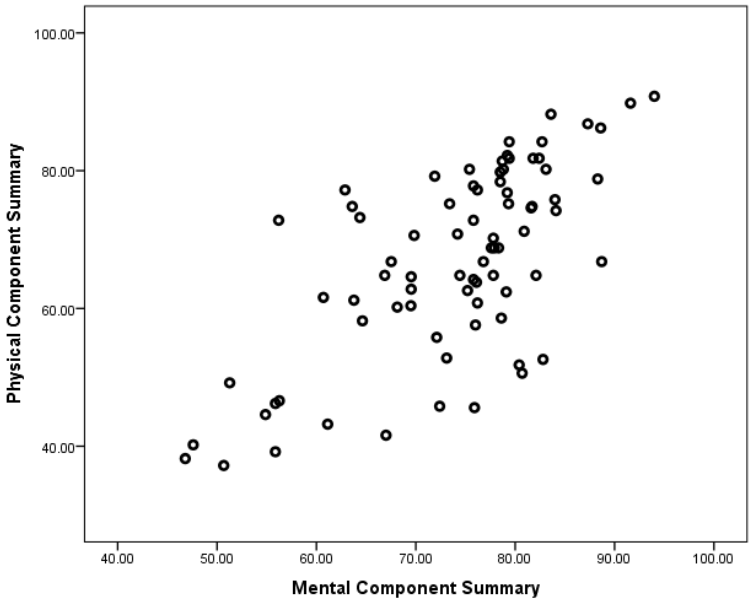


Figure 4.3(b): Correlation between PCS and MCS for comparison group.

Person's correlation coefficient (*r*): 0.687, p<0.001*

* denotes statistically significant at α=0.05

4.3.1.5 Correlation between Age and Health Related Quality of Life (HRQOL)

Overall, there were statistically significant negative weak correlations between age and PCS, age and MCS and age and total QOL. The correlation between age and PCS, age and MCS and age and total QOL for intervention group were slightly higher compared to comparison group (Table 4.19). It can be concluded that when the age increases, the scores of PCS, MCS and total QOL decreased.

Table 4.11: Correlation between Age and PCS, MCS and Total QOL

	Intervention (n=109)		**Comparison** (n=84)	
	r^a	**p-value**	r^a	**p-value**
Physical Component Summary (PCS)	-0.432	<0.001*	-0.425	<0.001*
Mental Component Summary (MCS)	-0.340	<0.001*	-0.305	<0.001*
Total Quality of life (QOL)	-0.420	<0.001*	-0.408	<0.001*

[a]: Pearson correlation coefficient; * denotes statistically significant at α=0.05

4.3.2 Self-perceived Depression, Anxiety and Stress

4.3.2.1 Baseline Scores of Self-perceived Depression, Anxiety and Stress

Table 4.20 shows the baseline mean (standard deviation) and median (interquartile) scores of self-perceived depression, anxiety and stress. Overall scores of self-perceived depression, anxiety and stress among the intervention group were slightly higher compared to comparison group. However, the median differences for self perceived depression, anxiety and stress were not significantly difference.

Table 4.12: Baseline score of Self-perceived Depression, Anxiety and Stress

	Intervention (n=109)		**Comparison** (n=84)		**Z**	**p-value**
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		
Depression*	5.3 (4.2)	4.0 (2.0)	4.8 (5.0)	4.0 (8.0)	-1.216	0.224[@]
Anxiety*	5.1 (3.7)	6.0 (2.0)	5.0 (4.1)	6.0 (6.0)	-1.782	0.075[@]
Stress*	6.7 (5.9)	6.0 (4.0)	6.4 (5.2)	6.0 (8.0)	-0.277	0.781[@]

SD: standard deviation; IQR: interquartile range
* skewed to the right; [@]: Mann Whitney U test

4.3.2.2 Categories of Self-perceived Depression, Anxiety and Stress among Intervention and Comparison Groups at Baseline

Overall, the proportions of self-perceived depression, anxiety and stress were 10.1 percent (95%CI: 9.0 – 20.0), 25.9 percent (95%CI: 20.0 – 34.1) and 5.7 percent (95%CI: 3.0 – 11.0) respectively. The categories of self-perceived depression, anxiety and stress are shown in Table 4.21. There were no patients having very severe depression, anxiety and stress. There were no significant differences in the self-perceived depression, anxiety and stress comparing both groups.

Table 4.13: Categories of Self-perceived Depression, Anxiety and Stress among Intervention and Comparison Groups at Baseline

	Classification	**Intervention** (n=109), Frequency (%)	**Comparison** (n=84). Frequency (%)	**Chi-square** (df)	**p-value**
Depression	Normal	98 (89.9)	72 (85.7)	1.959	0.581[#]
	Mild	6 (5.5)	7 (8.3)	(3)	
	Moderate	4 (3.7)	5 (6.0)		
	Severe	1 (0.9)	0 (0.0)		
Anxiety	Normal	83 (75.2)	60 (71.4)	4.466	0.215[#]
	Mild	8 (8.3)	14 (16.7)	(3)	
	Moderate	16 (14.7)	9 (10.7)		
	Severe	2 (1.8)	1 (1.2)		
Stress	Normal	103 (94.6)	79 (94.0)	2.976	0.393[#]
	Mild	2 (1.8)	4 (4.8)	(3)	
	Moderate	2 (1.8)	1 (1.2)		
	Severe	2 (1.8)	0 (0.0)		

Statistical test: [#] Fisher's exact test

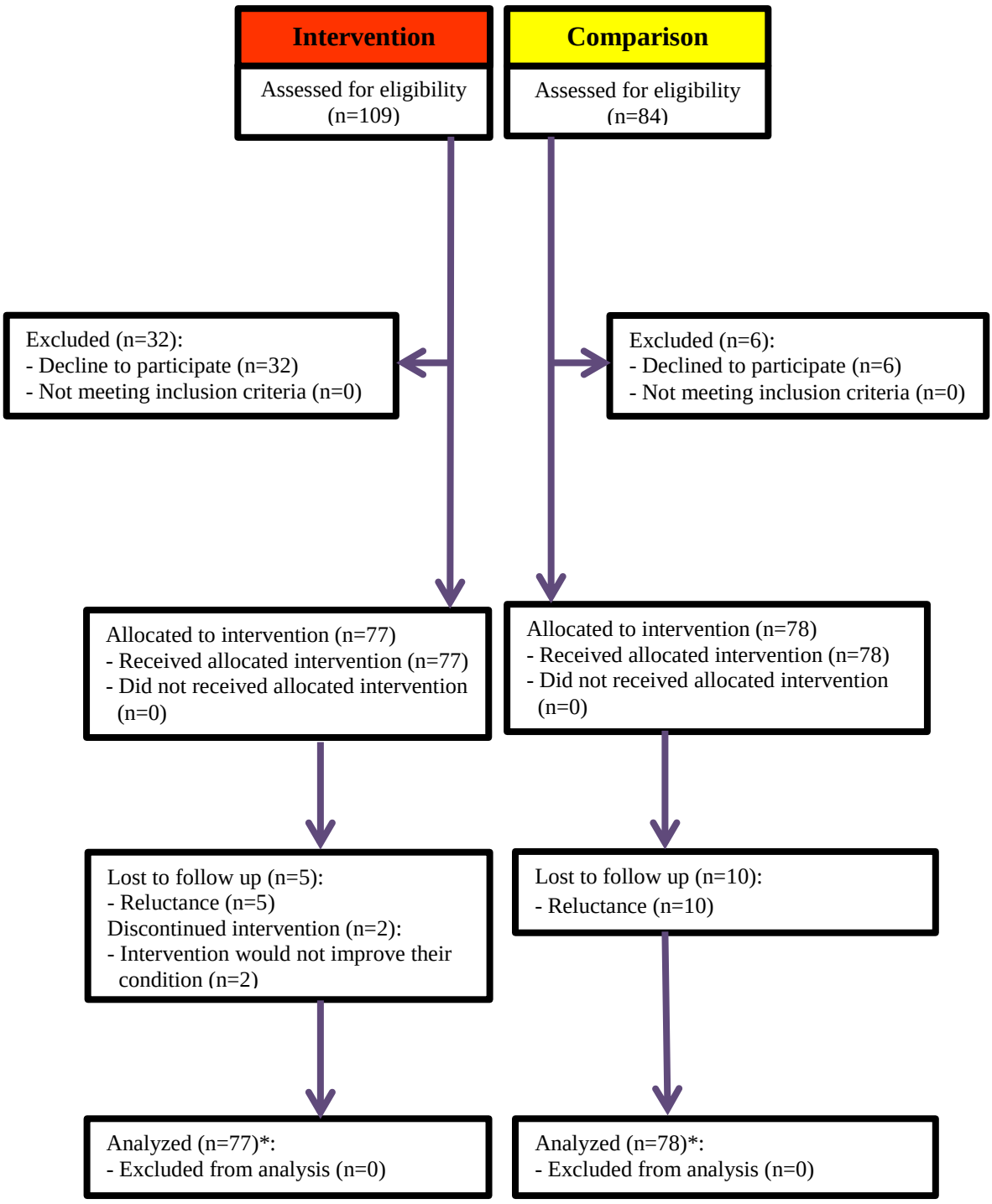
4.4 Process Evaluation

Process evaluation was designed to assess the extent to which programme procedures were carried out according to a written program plan. It provides information on what and how it was carried out and to assess what needs to change or improved.

4.4.1 Response and Completion Rates

There were 109 patients from UMMC and 84 patients form UKMMC eligible in the study. However, only 77 patients from the UMMC and 78 patients from UKMMC agreed to participate in the quasi experimental study, giving the response rate of 70.6 percent in the intervention group and 92.9 percent in the comparison group.

Only 70 patients in the intervention group and 68 patients in comparison group completed the study. This gave a completion rate of 90.9 percent in the intervention group and 87.2 percent in the comparison group (Figure 4.4). Each non-respondent was given three telephone call reminders before considering them as non-respondents. The most frequently cited reasons given by the respondents were reluctance (88.2 percent) and 11.2 percent felt that the intervention would not improve their condition. The analysis in this study was based on the intention-to-treat analysis. Therefore, 78 patients in the intervention group and 77 in the comparison group were involved in the analysis.



*: Intention to treat analysis

Figure 4.4: The flow diagram of the progress at different phases of study in intervention and comparison groups.

4.4.2 Characteristics of Respondents and Non-respondents

Table 4.22 shows the socio-demographic and life style characteristics of the respondents and non-respondents. There were no significant difference in the socio-demographic characteristics and lifestyle behaviour between the respondents and non-respondents.

Table 4.14: Socio-demographic characteristics and some lifestyles of the Respondents (R) and Non-respondents (NR)*

	Intervention (n=77)				**Comparison** (n=78)			
	R (n=70), Mean (SD)	**NR** (n=7), Mean (SD)	**R** (n=70), Frequency(%)	**NR** (n=7), Frequency(%)	**R** (n=68), Mean (SD)	**NR** (n=10), Mean (SD)	**R** (n=68), Frequency(%)	**NR** (n=10), Frequency(%)
Age	71.4 (7.2)	68.7 (5.3)			73.1 (7.6)	76.4 (6.7)		
Chinese			30 (42.9)	6 (85.7)			32 (47.1)	5 (50.0)
Married			63 (90.0)	6 (85.7)			63 (92.6)	8 (80.0)
Living with family/partner			67 (95.7)	6 (85.7)			65 (95.6)	8 (80.0)
Secondary education			36 (51.4)	3 (42.9)			43 (63.2)	8 (80.0)
Ever smoke			36 (51.4)	4 (57.1)			42 (61.8)	5 (50.0)
Never drink			21 (30.0)	1 (14.2)			22 (32.4)	3 (10.0)

* All above characteristic showed no significance differences between the Respondents (R) and Non Respondents (NR) respective intervention and comparison groups

4.4.3 Completion Rate

Figure 4.5 shows the completion rate for intervention and comparison groups for the six months follow up using the number at baseline as the denominator.

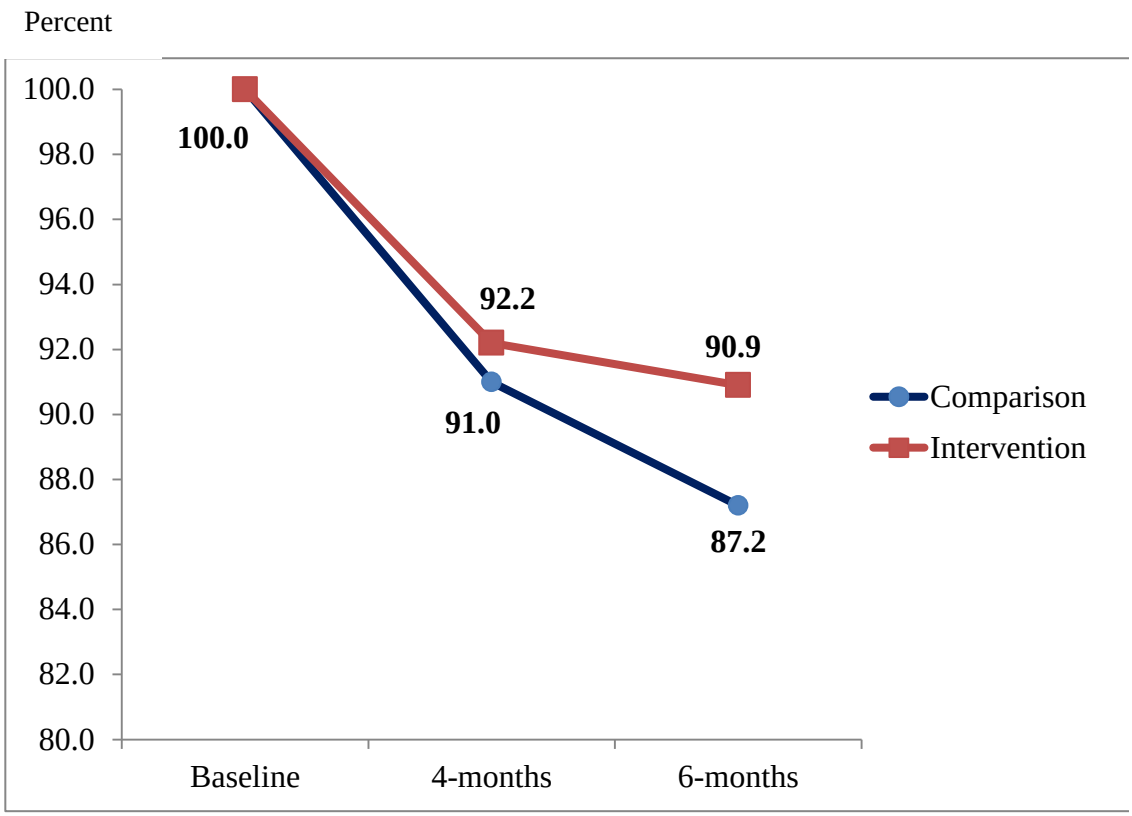


Figure 4.5: Completion rates for intervention and comparison groups

At the 4-month, 6 patients from the intervention group and 7 patients from comparison group did not continue the study. At the 6-month, 1 patient from intervention group and 3 patients from comparison group did not continue the study. The intervention group had a better completion rate compared to the comparison group (90.9 percent vs 87.2 percent). However, there was no significant difference in the completion rate in both group ($p>0.05$).

4.4.4 The Frequency of Applied Progressive Muscle Relaxation Training (APMRT) Conducted

The intervention group was given the applied progressive muscle relaxation training (APMRT) three times at two weeks intervals. The APMRT consisted of six modules carried out in approximately two hours. The therapy was given either at the rehabilitation clinic, UMMC by occupational therapist or by the principal investigator at the patients' home if they cannot go to the rehabilitation clinic.

A total of 70 (90.9 percent) patients were given the APMRT by the principal investigator at their home with a total of 189 sessions. Meanwhile, seven (9.1 percent) patients received the APMRT from the occupational therapist at the rehabilitation clinic with a total of 21 sessions. Table 4.14(a) and 4.14(b) show the comparison of the patients' scores of physical component summary (PCS), mental component summary (MCS), and total quality of life (QOL); and self-perceived depression, anxiety and stress between the APMRT given by the principal investigator and occupational therapist. Overall, there were no significant differences in all scores at baseline, 4-months and 6-months by the principal investigator (PI) or occupational therapist (OT).

Table 4.15(a): Comparison of patients' Scores of Physical Component Summary (PCS), Mental Component Summary (MCS) and Total Quality of Life (QOL) given by the Principal Investigator (PI) and Occupational Therapist (OT)

	APMRT given by	**N**	**Patients' Scores**, Mean (SD)	**t (df)**	**Mean diff.** (95%CI)	**p-value**
PCS (Baseline)	PI	70	67.87 (17.55)	0.090 (75)	0.62 (-13.41, 14.68)	0.928
	OT	7	67.23 (20.31)			
PCS (4-months)	PI	70	68.23 (17.54)	0.086 (75)	0.60 (-13.44, 14.64)	0.932
	OT	7	67.63 (20.30)			
PCS (6-months)	PI	70	69.04 (17.50)	0.073 (75)	0.51 (-13.50, 14.52)	0.942
	OT	7	68.53 (20.30)			
MCS (Baseline)	PI	70	73.49 (14.02)	0.400 (75)	2.30 (-9.17, 13.77)	0.690
	OT	7	71.19 (19.33)			
MCS (4-months)	PI	70	76.87 (12.42)	-0.344 (75)	-1.70 (-11.85, 8.44)	0.739
	OT	7	78.56 (17.01)			
MCS (6-months)	PI	70	79.53 (10.71)	-0.155 (75)	-0.69 (-9.54, 8.15)	0.877
	OT	7	80.22 (15.78)			
Total QOL (Baseline)	PI	70	70.68 (15.14)	-0..238 (75)	1.47 (-10.81, 13.75)	0.812
	OT	7	69.21 (19.61)			
Total QOL (4-months)	PI	70	71.63 (13.99)	-0.082 (75)	-0.46 (-11.75, 10.82)	0.935
	OT	7	72.10 (17.33)			
Total QOL (6-months)	PI	70	72.02 (13.43)	-0.027 (75)	0.15 (-10.77, 11.06)	0.979
	OT	7	71.87 (17.65)			

PI: Principal Investigator; OT: Occupational therapist;
CI: Confidence intervals; SD: standard deviation; [@]:
Statistical test: independent t-test

Table 4.15(b): Comparison of Patients' scores of self-perceived Depression, Anxiety and Stress given by the Principal Investigator (PI) and Occupational Therapist (OT)

	APMRT given by	**N**	**Patients' scores,** Median (IQR)	**Mean Rank**	***Z***	**p-value**
Depression (Baseline)	PI	70	4.00 (2.00)	41.78	-1.674	0.094
	OT	7	4.00 (2.00)	27.14		
Depression (4-months)	PI	70	4.00 (2.00)	41.77	-1.666	0.096
	OT	7	4.00 (2.00)	27.22		
Depression (6-months)	PI	70	4.00 (2.00)	41.77	-1.666	0.096
	OT	7	4.00 (2.00)	27.21		
Anxiety (Baseline)	PI	70	6.00 (4.00)	40.27	-0.299	0.765
	OT	7	6.00 (0.00)	42.93		
Anxiety (4-months)	PI	70	6.00 (6.00)	40.47	-0.043	0.965
	OT	7	6.00 (2.00)	40.86		
Anxiety (6-months)	PI	70	4.00 (6.00)	40.64	-0.173	0.863
	OT	7	4.00 (4.00)	39.07		
Stress (Baseline)	PI	70	4.00 (6.00)	40.90	-0.513	0.608
	OT	7	4.00 (6.00)	36.29		
Stress (4-months)	PI	70	4.00 (6.00)	40.64	-0.182	0.856
	OT	7	4.00 (6.00)	39.00		
Stress (6-months)	PI	70	4.00 (6.00)	40.42	-0.104	0.917
	OT	7	4.00 (6.00)	41.36		

PI: Principal Investigator; OT: Occupational therapist;
IQR: interquartile-range;
Statistical test: Mann Whitney U test

4.4.5 Frequency of Practicing APMRT at Home

The patients were recommended to carry out APMRT twice daily. They were required to fill in a log book the frequency of practising the therapy at home. However, the completion rate of the log book was very poor. Less than 10 percent returned the log books. Even though the patients returned the log books, majority of them did not monitor how many times they practiced the therapy at home. So, the correlation between the frequency of practicing APMRT and the scores of PCS, MCS, total QOL, depression, anxiety and stress cannot be carried out due to very high rate of missing data.

4.4.6 Frequencies of Telephone Calls

Telephone calls were made biweekly throughout the six months study period to avoid loss to follow up. A total of 1150 telephone calls were made with an average of 14.9 calls (range: 14 – 16) per patient in the intervention group.

4.5 Comparison Group

The comparison group was only given information on depression, anxiety and stress; health education on how to achieve better quality of life and solving psychological problems. A talk on healthy lifestyles was also given to them. A total of 1155 telephone calls have been made with an average of 14.8 calls (range: 14 – 16) per patient in the comparison group.

4.6 Outcome Evaluation

Outcome evaluation was assessed whether the APMRT achieved its objectives such as improvement on HRQOL (physical component summary, mental component summary and total quality of life) and psychological problems (depression, anxiety and stress).

4.6.1 Health Related Quality of Life (HRQOL)

The assessment for the impact of APMRT on the HRQOL in this study was classified into three parts which were: physical component summary (PCS), mental component summary (MCS) and overall quality of life (QOL). The higher the mean score for PCS, MCS and overall QOL indicate better outcomes.

4.6.1.1 Physical Component Summary (PCS)

4.6.1.1.1 Mean Score of PCS throughout the Study

There was no difference in the PCS score for the intervention group from baseline to 6-months. However, there was a small increase at 4-months. For comparison group, there was a small increase at 4-months and a small reduction at 6-months (Figure 4.6).

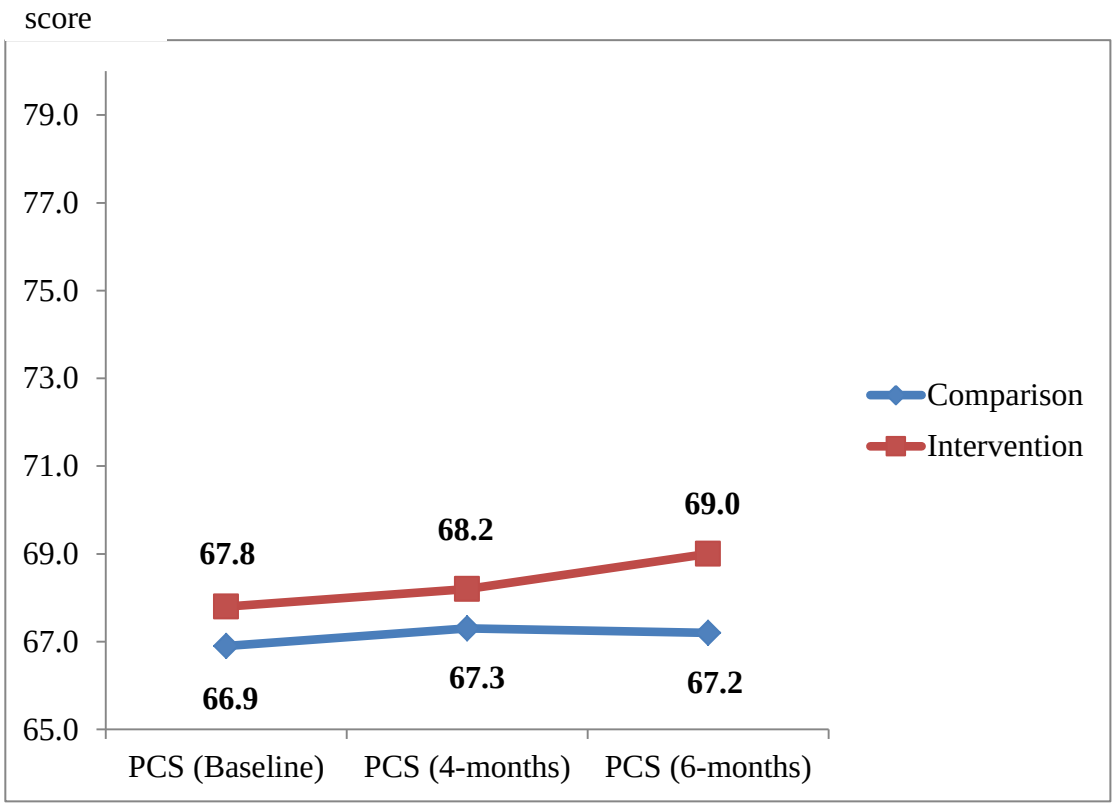


Figure 4.6: Score of the Physical Component Summary (PCS) for both intervention and comparison groups

There were no significant differences in the mean PCS scores at baseline [mean difference: 0.92 (95%CI: (-4.11, 5.94), p=0.719], 4-months [mean difference: 0.90 (95%CI: (-4.14, 5.95), p=0.724] and 6-months [mean difference: 1.58 (95%CI: (-3.43, 6.60), p=0.535] between intervention and comparison groups.

4.6.1.1.2 Between-subject Effects for PCS

Table 4.24 shows the comparison for the mean PCS scores between intervention and comparison groups for between-subject effects for the interaction between time and group.

Table 4.16: Comparison of PCS scores between two study groups.

	Time	Intervention (n=77)	Comparison (n=78)	F stat (df)[a]	p-value[a]	Partial effect size, (partial η^2)
		Mean (SD)	Mean (SD)			
Time * Group	Baseline	67.8 (17.7)	66.9 (13.8)	0.199 (1,153)	0.656	0.001
	4-months	68.2 (17.6)	67.3 (14.0)			
	6-months	69.0 (17.6)	67.4 (13.8)			

[a] Repeated measures ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the pattern of PCS (3 repeated measurements) between two study groups]
SD: standard deviation; df: degree of freedom

For in between-subject effect, there was no significant difference between intervention and comparison groups (p=0.656). It is observed that APMRT did not produce any effect on PCS score.

4.6.1.1.3 Within-subject Effects for PCS

Table 4.25 shows paired differences for mean PCS score from baseline to 4-months, baseline to 6-months and 4-months to 6-months in intervention and comparison groups.

Table 4.17: Paired differences for Mean PCS score from baseline to 4-months, baseline to 6-months and 4-months to 6-months in intervention and comparison groups.

	Intervention (n=77)			**Comparison** (n=78)		
	t (df)	**Paired difference** (95%CI)	**p-value**	**t (df)**	**Paired difference** (95%CI)	**p-value**
Baseline vs 4-months	-29.989 (76)	0.39 (0.19, 0.99)	<0.001*	-0.941 (77)	-0.38 (-1.19, 0.43)	0.350
Baseline vs 6-months	-28.76 (76)	1.19 (1.10, 1.27)	<0.001*	-22.882 (77)	0.52 (0.47, 0.56)	<0.001*
4-months vs 6-months	-27.56 (76)	0.82 (0.75, 0.88)	<0.001*	-0.344 (77)	-0.14 (-0.95, 0.67)	0.732

* statistically significant at α=0.05
CI: confidence intervals
Statistical test: independent t-test

In the intervention group, there were significant paired differences in the PCS score from baseline to 4-months; from 4-months to 6-months; and from baseline to 6-months. Meanwhile, among comparison group, there were no significant paired differences from baseline to 4-months and from baseline to 6-months. However, there was a significant paired difference from 4-months to 6-months.

4.6.1.1.4 Post-hoc Multiple Comparison of score of PCS

There was no significant interaction between time and group (within-subject effect) [$F(2,306)=2.449$, $p=0.072$, partial $\eta^2=0.017$]. This indicated that the PCS score for intervention group did not increase significantly compared to comparison group.

4.6.1.2 Mental Component Summary (MCS)

4.6.1.2.1 Mean Score of MCS throughout the Study

Figure 4.7 shows the mean score of MCS for both intervention and comparison groups.

score

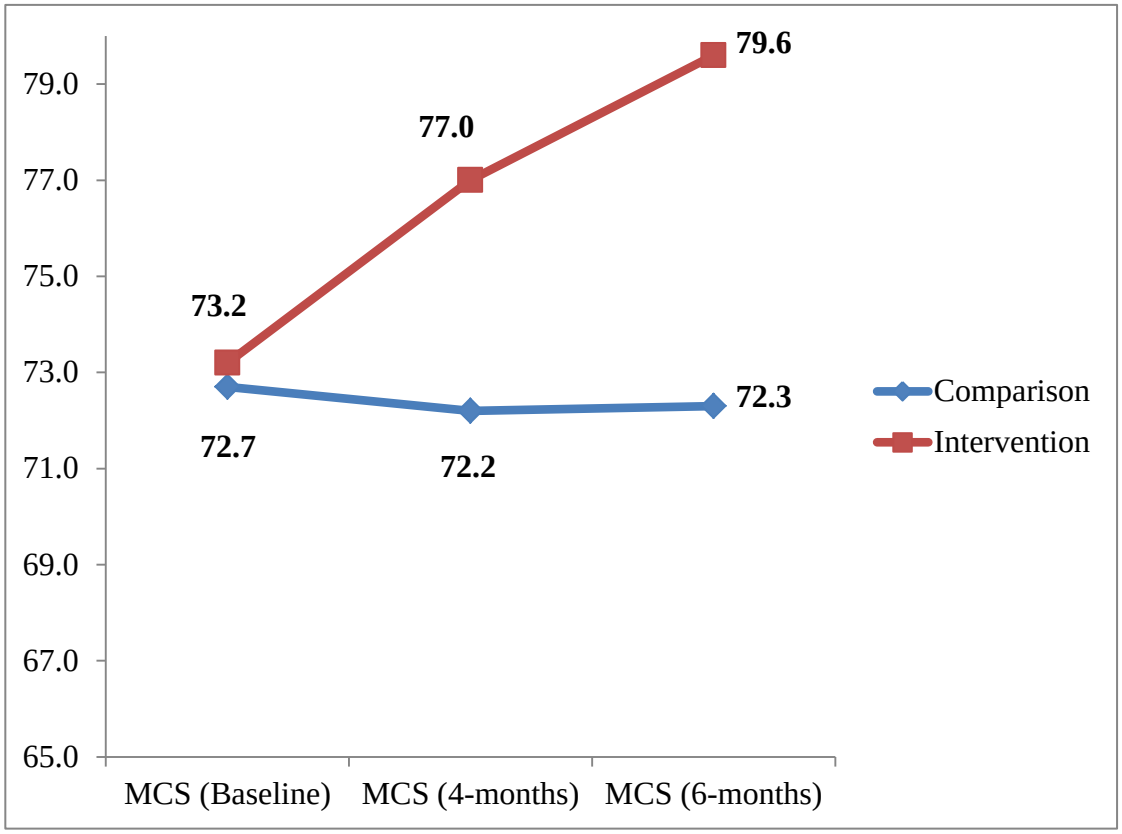


Table 4.7: Mean score of MCS for both intervention and comparison group

For the intervention group, the mean MCS score increased substantially from baseline to 4-months as well as from 4-months to 6-months. For the comparison group, the mean MCS score decreased slightly from baseline to 4-months but did not change from 4-months to 6-months. There were significant differences in the mean MCS scores at 4-months [mean difference: 4.82 (95%CI: 1.15, 8.50), p=0.010] and 6-months [mean difference: 7.40 (95%CI: 3.99, 10.80), p<0.001]. However, there was no significant difference at baseline between intervention and comparison groups [mean difference: 0.54 (95%CI: -3.46, 4.55), p=0.790].

4.6.1.2.2 Between-subject Effects for MCS

Table 4.26 shows the comparison for the mean MCS scores between intervention and comparison groups for between-subject effects for the interaction between time and group.

Table 4.18: Comparison of MCS scores between two study groups.

	Time	Intervention (n=77)	Comparison (n=78)	F stat (df)[a]	p-value[a]	Partial effect size, (partial η^2)
		Mean (SD)	Mean (SD)			
Time * Group	Baseline	73.3 (14.4)	72.7 (10.6)	5.636 (1,153)	0.019*	0.236
	4-months	77.0 (12.8)	72.2 (10.3)			
	6-months	79.6 (11.1)	72.2 (10.2)			

[a] Repeated measures ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the pattern of PCS (3 repeated measurements) between two study groups]
SD: standard deviation; df: degree of freedom

For in between-subject effect, there was a significant difference in the MCS score (3 repeated measurements) between the intervention and comparison group (p=0.019). It was found that the MCS score for intervention group increased significantly compared to that of comparison group. The effect size accounted for MCS score was small (23.6 percent).

4.6.1.2.3 Within-subject Effects for MCS

Table 4.27 shows paired differences for mean MCS score from baseline to 4-months, baseline to 6-months and 4-months to 6-months in the intervention and comparison groups.

Table 4.19: Paired differences for mean MCS score from baseline to at 4-months, baseline to at 6-months and at 4-months to at 6-months in intervention and comparison groups.

	Intervention (n=77)			**Comparison** (n=78)		
	t (df)	**Paired difference** (95%CI)	p-value	**t (df)**	**Paired difference** (95%CI)	p-value
Baseline vs 4-months	-3.724 (76)	3.74 (1.74, 5.74)	0.001*	2.717 (77)	-0.54 (-0.94, -0.14)	0.008*
Baseline vs 6-months	-6.713 (76)	6.32 (4.44, 8.28)	<0.001*	2.719 (77)	-0.54 (-0.94, -0.15)	0.009*
4-months vs 6-months	-2.851 (76)	2.57 (0.77, 4.37)	0.006*	-1.000 (77)	-0.01 (-0.02, 0.03)	0.320

* statistically significant at α=0.05
Statistical test: independent t-test

In the intervention group, there were significance paired differences in the MCS score from baseline to 4-months, baseline to 6-months and from 4-months to 6-months. Meanwhile, among the comparison group, there were significant paired differences from baseline to 4-months and baseline to 6-months, but no significant paired difference from 4-months to 6-months.

4.6.1.2.4 Post-hoc Multiple Comparison of score of MCS

There was a significant interaction between time and group for within-subject effect [$F(2,306) = 26.130$, $p<0.001$, partial $\eta^2=0.146$]. The intervention group had increased MCS score which was statistically significant compared to comparison group. The effect size for the MCS score by APMRT was small (14.6 percent).

Table 4.28 shows the post-hoc comparison of score of MCS using Bonferroni procedure between intervention and comparison groups for MCS (Interaction between Time and group).

Table 4.20: Post-hoc comparison of score of MCS (Interaction between Time and group) between two study groups at each pair of time level.

Level		**F stat** (df)[a]	**Mean difference** (95%CI)	**p-value**[a,b]	**Partial effect size**, (partial η^2)
Time * Group	Baseline to 4-months	17.693 (1,153)	4.11 (2.68, 7,54)	<0.001*	0.104
	4-months to 6-months	12.389 (1,153)	2.21 (0.68, 5.54)	0.001*	0.075

[a] Repeated Measure ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the score of MCS (2 repeated measurements) between two study groups]
[b] p-values are adjusted for multiple comparison using Bonferroni procedure
* denotes statistically significant at α=0.05
df: degree of freedom; CI: confidence intervals

It indicated that there was a significant difference in the mean difference of MCS score in the intervention and comparison groups from baseline to 4-months ($p<0.001$). The mean difference of the MCS score of the intervention group was significantly higher compared to the mean difference in the comparison group. The effect size accounted for MCS score by APMRT from baseline to 4-months was small (10.4 percent).

There was also a significant difference in the mean difference of MCS score in the intervention and comparison groups from 4-months to 6-months ($p=0.001$). The mean difference of the MCS score in intervention group was significantly higher compared to the mean difference in the comparison group. The effect size accounted for MCS score from 4-months to 6-months by APMRT was small (7.5 percent).

4.6.1.2.4 Within-subject Contrast for MCS

The within-subject contrast for MCS score (Interaction between Time and group) is shown in Table 4.29.

Table 4.21: Within-subject contrast for MCS.

	Trend	**F (df)**	**p-value**	**Partial effect size**, (partial η^2)
Time * Group	Linear	51.447 (1,153)	<0.001*	0.252
	Quadratic	1.056 (1,153)	0.706	0.007

* statistically significant at $\alpha=0.05$
df: degree of freedom
Statistical test: Repeated Measure ANOVA (Time & Group Interaction Effect)

There were significant linear trends in time and interaction in time and group (intervention and comparison). The effect sizes accounted for linear trend in time and interaction between time and group in MCS score were 25.2 percent. It can be concluded that APMRT have a relatively small effect in linear trend in interaction between time and group in increasing MCS score.

4.6.1.3 Total Quality of Life (QOL)

4.6.1.3.1 Mean Score of Total QOL throughout the Study

Figure 4.8 shows the score of total QOL for the intervention and comparison groups. For the intervention group, the mean total QOL score increased modestly from baseline to 4-months, followed by a minimal increase from 4-months to 6-months. For the comparison group, the mean total QOL score was minimally increased from 4-months to 6-months following no change from baseline to 4-months.

score

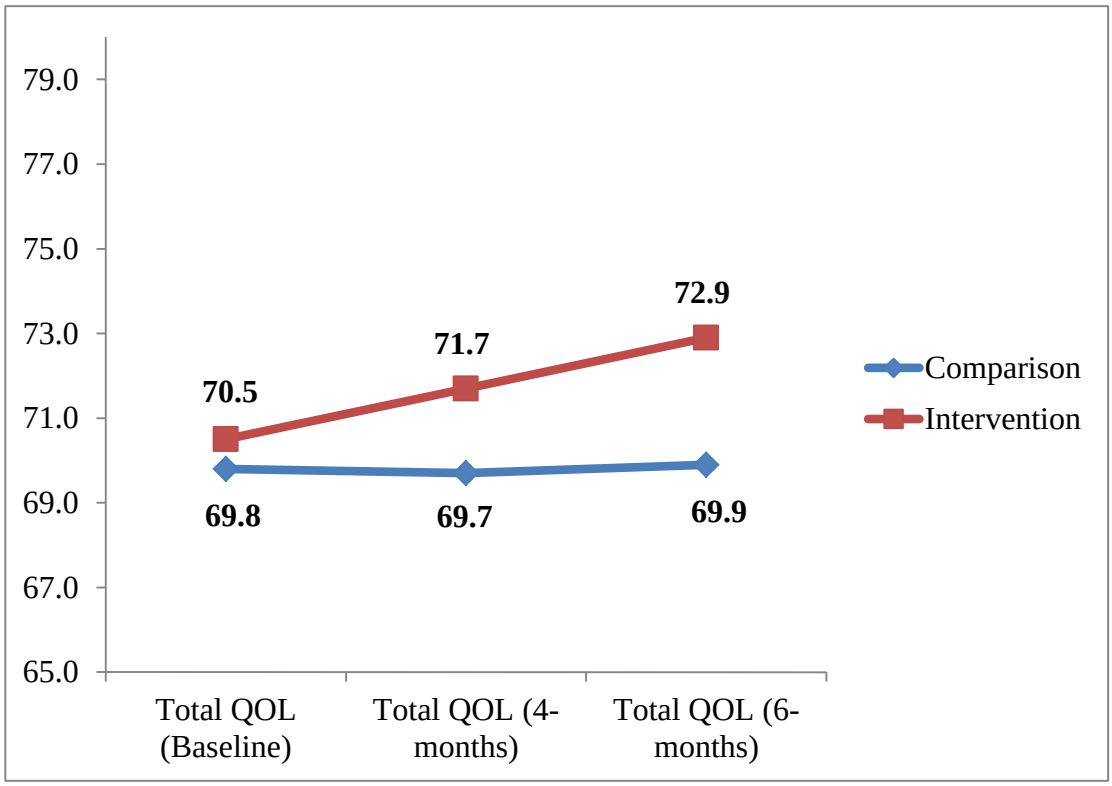


Figure 4.8: The score of the total quality of life (QOL) for both intervention and comparison groups

There were no significant differences in the mean total QOL scores at baseline [mean difference: 0.73 (95%CI: -3.53, 4.99), p=0.736], 4-months [mean difference: 1.94 (95%CI: -2.10, 5.98), p=0.344] and 6-months [mean difference: 2.07 (95%CI: -1.88, 6.02), p=0.302] in between the groups.

4.6.1.3.2 Between-subject Effects for total QOL

Table 4.30 shows the comparison for mean total QOL scores between intervention and comparison groups for between-subject effects for the interaction between time and group.

Table 4.22: Comparison of total QOL scores between two study groups.

	Time	**Intervention** (n=77) Mean (SD)	**Comparison** (n=78) Mean (SD)	**F stat** (df)[a]	**p-value**[a]	**Partial effect size**, (partial η^2)
Time * Group	Baseline	70.5 (15.4)	69.8 (11.1)	4.322 (1,153)	0.045*	0.051
	4-months	71.7 (14.2)	69.7 (11.1)			
	6-months	72.0 (13.7)	69.9 (11.0)			

[a] Repeated measures ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the pattern of PCS (3 repeated measurements) between two study groups]
SD: standard deviation; df: degree of freedom

In between-subject effect, there was a significant increase in total QOL score (3 repeated measurements) between the intervention and comparison groups (p=0.045). The effect size produced by APMRT for total QOL was small (5.1 percent). It was found that the total QOL score for intervention group increased significantly compared to that of comparison group.

4.6.1.3.3 Within-subject Effects for total QOL

Table 4.31 shows paired differences for mean total QOL score from baseline to 4-months, baseline to 6-months and 4-months to 6-months in intervention and comparison groups.

Table 4.23: Paired differences for mean total QOL score from baseline to at 4-months, baseline to 6-months and 4-months to 6-months in intervention and comparison groups

	Intervention (n=77)			**Comparison** (n=78)		
	t (df)	**Paired difference** (95%CI)	**p-value**	**t (df)**	**Paired difference** (95%CI)	**p-value**
Baseline vs 4-months	-2.267 (76)	1.13 (0.13, 2.12)	0.026*	0.341 (77)	0.08 (-0.38, 0.54)	0.734
Baseline vs 6-months	-3.192 (76)	1.47 (0.55, 2,38)	0.002*	-1.188 (77)	-0.12 (-0.32, 0.08)	0.238
4-months vs 6-months	-0.740 (76)	-0.33 (-1.22, 0.56)	0.462	-0.986 (77)	-0.20 (-0.61, 0.20)	0.327

* statistically significant at α=0.05
CI: confidence intervals
Statistical test: independent t-test

Among intervention group, there were significant paired differences in the total QOL score from baseline to 4-months and from baseline to 6-months but no significant paired difference from 4-months to 6-months. Meanwhile, among comparison group there were no significant paired differences throughout the study period.

4.6.1.3.4 Post-hoc Multiple Comparison for Score of total QOL

There was significant interaction between time and group for within-subject effect [$F(2,306) = 4.329$, $p=0.014$, partial $\eta^2=0.028$]. The total QOL in the intervention group was increased significantly compared to that in the comparison group. The effect size accounted for the total QOL score by APMRT was small (2.8 percent).

Table 4.32 shows the post-hoc comparison of score of total QOL using Bonferroni procedure between intervention and comparison groups for total QOL (Interaction between Time and group).

Table 4.24: Post-hoc comparison of score of total QOL (Interaction between Time and group) between two study groups at each pair of time level

Level		**F stat** (df)[a]	**Mean difference** (95%CI)	**p-value**[a,b]	**Partial effect size**, (partial η^2)
Time * Group	Baseline to 4-months	4.887 (1,153)	0.77 (0.03, 1.24)	0.029*	0.031
	4-months to 6-months	0.072 (1,153)	0.26 (-0.29, 0.80)	0.798	0.001

[a] Repeated Measure ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the score of MCS (2 repeated measurements) between two study groups]
[b] p-values are adjusted for multiple comparison using Bonferroni procedure
* denotes statistically significant at α=0.05
df: degree of freedom; CI: confidence intervals

There was a significant mean difference for total QOL score in the intervention and comparison groups from baseline to at 4-months ($p<0.001$). The mean difference of the total QOL score of the intervention group was significantly higher compared to the mean difference in the comparison group. The effect size accounted for total QOL by APMRT from baseline to at 4-months was small (3.1 percent). However, there was no significant difference in the mean difference of total QOL score in the intervention and comparison group from at 4-months to at 6-months ($p=0.798$).

4.6.1.3.4 Within-subject Contrast for Total QOL

The within-subject contrast for total QOL score (Interaction between Time and group) is shown in Table 4.33.

Table 4.25: Within-subject contrast for total QOL

	Trend	**F (df)**	**p-value**	**Partial effect size**, (partial η^2)
Time * Group	Linear	12.007 (1,153)	0.011*	0.061
	Quadratic	0.763 (1,153)	0.489	0.003

* statistically significant at $\alpha=0.05$
df: degree of freedom
Statistical test: Repeated Measure ANOVA (Time & Group Interaction Effect)

There were significant linear trends in time and in the interaction between time and group (intervention and comparison). The effect sizes accounted for linear trend in time and interaction time and group in total QOL score were smalls (6.1 percent). It

was concluded that APMRT shows a relatively small effect in linear trend in time and in an interaction between time and group in increasing total QOL score.

4.6.1.4 Self-reported health transition of the participants at baseline and 6-month of the study

Self-reported health transition among participants in the study at baseline and 6-months are shown in Table 4.34. There were no significant differences in self-reported health transition over six month's period in both groups. Most participants reported the same health condition.

Table 4.26: Self-reported health transition of the participants at baseline and 6-month of the study

Classifications	**Intervention** (n=70)				**Comparison** (n=68)			
	at baseline, Frequency (%)	**at 6-month**, Frequency (%)	**Chi-square (df)**	**p-value**	**at baseline**, Frequency (%)	**at 6-month**, Frequency (%)	**Chi-square (df)**	**p-value**
Better now than 1-year ago	18 (23.4)	22 (28.6)	4.563 (2)	0.102	20 (25.6)	18 (23.1)	0.257 (2)	0.879
About the same	47 (61.0)	51 (66.2)			55 (70.5	56 (71.8)		
Worse now than 1-year ago	12 (15.6)	4 (5.2)			3 (3.8)	4 (5.1)		

Statistical test: Chi-square test

4.6.2 Self-perceived Depression, Anxiety and Stress

In this study, assessments for the impact of APMRT on psychological problem were depression, anxiety and stress. The lower the mean score for depression, anxiety and stress, the better outcome. The raw data for depression, anxiety and stress scores were not normally distributed (skewed to the right). Transformation was carried out to normalize the data by using the formula of Log_{10} (x+1). The end product of the analysis was retransformed back to the normal value by using the formula $antilog_{10} - 1$.

4.6.2.1 Depression

4.6.2.1.1 Mean Score of Depression throughout the Study

Figure 4.9 shows the mean score of depression for the intervention and comparison groups. For the intervention group, the mean depression score decreased minimally from baseline to 6-months. For the comparison group, the mean depression score increased slightly from baseline to 4-months but did not change from 4-months to 6-months.

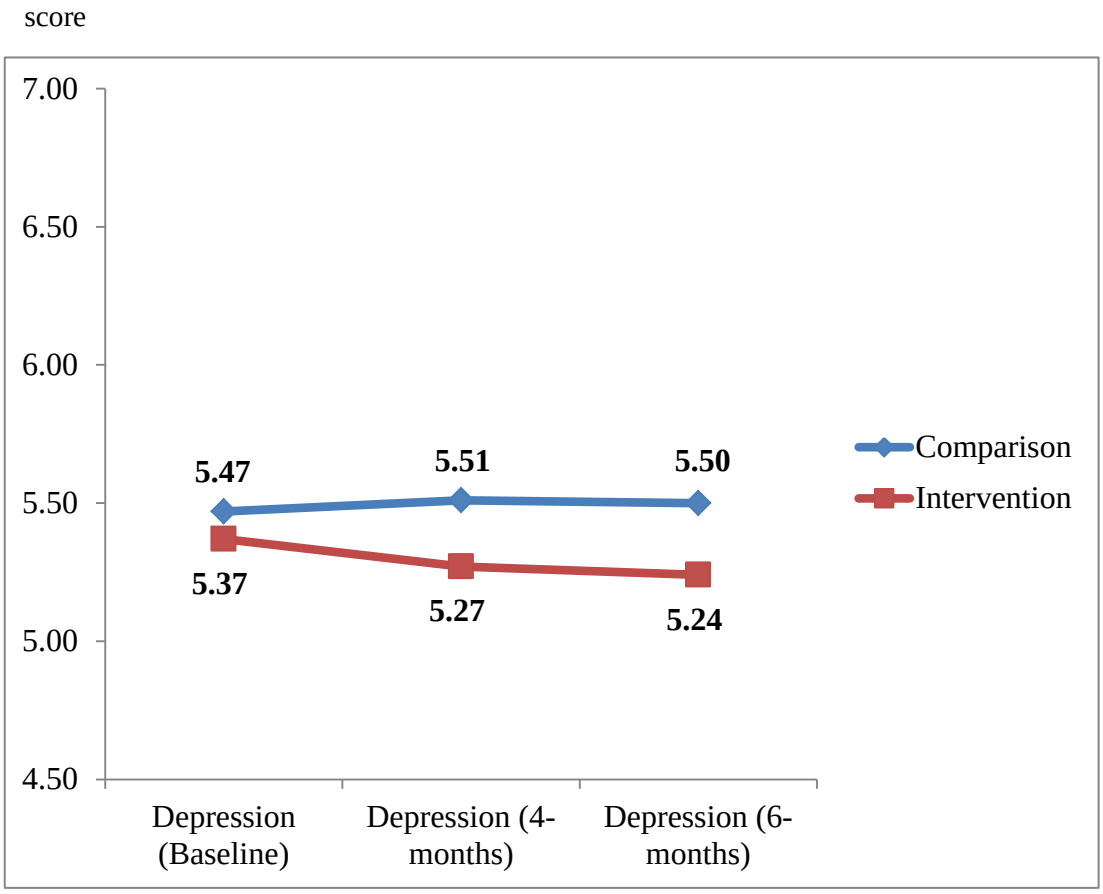


Figure 4.9: Score of Depression for both intervention and comparison groups

There were no significant differences in the mean depression scores at baseline [mean difference: -0.06 (95%CI: -1.47, 1.35), p=0.934], 4-months [mean difference: -0.24 (95%CI: -1.58, 1.10), p=0.724] and 6-months [mean difference: -0.27 (95%CI: -1.59, 1.06), p=0.693] between intervention and comparison groups.

4.6.2.1.2 Between-subject Effects for Depression score

Table 4.35 shows the comparison for the mean depression scores between intervention and comparison groups for between-subject effects for the interaction between time and group.

Table 4.27: Comparison of Depression scores between two study groups.

	Time	Intervention (n=77) Mean (SD)	Comparison (n=78) Mean (SD)	F stat (df)[a]	p-value[a]	Partial effect size, (partial η^2)
Time * Group	Baseline	5.37 (4.21)	5.43 (3.74)	0.687 (1,153)	0.784	0.059
	4-months	5.27 (3.87)	5.51 (4.54)			
	6-months	5.24 (3.77)	5.52 (4.54)			

[a] Repeated measures ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the pattern of PCS (3 repeated measurements) between two study groups]
SD: standard deviation; df: degree of freedom

There was no significant difference between intervention and comparison groups (p=0.784) in between the group. APMRT did not produce any effect in depression score. It is observed that APMRT did not produce any effect on PCS score.

4.6.2.1.3 Within-subject Effects for Depression score

Table 4.36 shows the paired differences for mean depression score from baseline to 4-months, baseline to 6-months and 4-months to 6-months in intervention and comparison groups. It was found that in both groups, there were no significant paired mean differences from baseline to 4-months, baseline to 6-months and from 4-months to 6-months.

Table 4.28: Paired differences for mean depression score from baseline to 4-months, baseline to 6-months and 4-months to 6-months in intervention and comparison groups

	Intervention (n=77)			**Comparison** (n=78)		
	t (df)	**Paired difference** (95%CI)	**p-value**	**t (df)**	**Paired difference** (95%CI)	**p-value**
Baseline vs 4-months	1.651 (76)	-0.10 (-0.23, 0.02)	0.103	-1.012 (77)	0.07 (-0.07, 0.24)	0.323
Baseline vs 6-months	1.520 (76)	-0.13 (-0.30, 0.04)	0.133	-1.000 (77)	0.07 (-0.08, 0.23)	0.320
4-months vs 6-months	1.000 (76)	0.03 (-0.08, 0.02)	0.320	-0.003 (77)	0.01 (-0.03, 0.14)	0.999

CI: confidence intervals
Statistical test: independent t-test

4.6.2.1.4 Post-hoc Multiple Comparison for Score of Depression

There was a non-significant interaction between time and group (within-subject effect) [F(1.057, 143.753)=0.073, p=0.801, partial η^2=0.001]. This indicated that the depression score for intervention group did not increase significantly even after metastases status adjustment compared to comparison group.

4.6.2.2 Anxiety

4.6.2.2.1 Mean Score of Anxiety throughout the Study

Figure 4.10 shows the mean score of anxiety for the intervention and comparison groups. For the intervention group, the mean anxiety score decreased substantially from baseline to 4-months as well as from 4-months to 6-months. For the comparison group, the mean anxiety score increased slightly from baseline to at 4-months, followed by minimal increase from 4-months to 6-months.

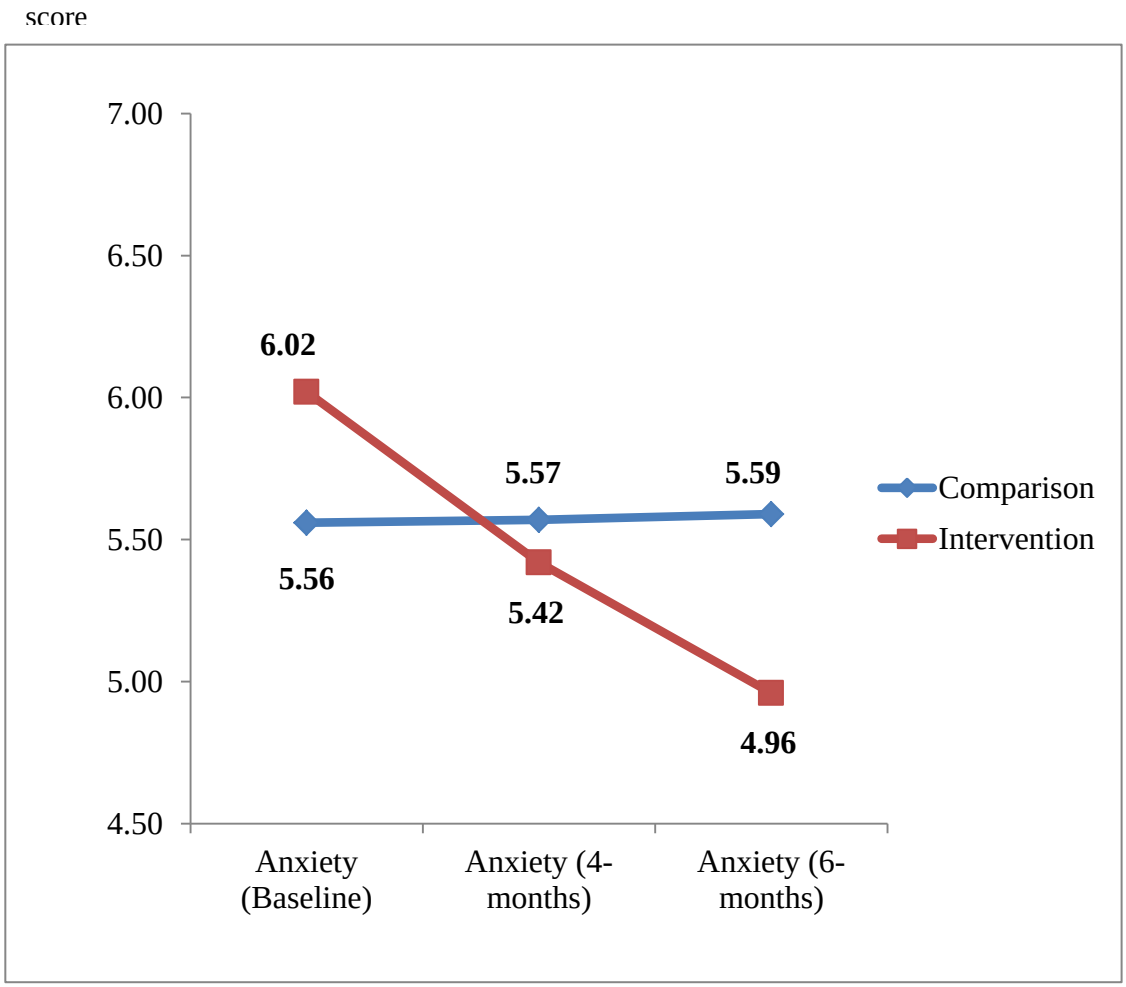


Figure 4.10: Score of the Anxiety for both intervention and comparison groups

There were no significant differences in the mean anxiety scores at baseline [mean difference: 0.46 (95%CI: -0.76, 1.68), p=0.457], 4-months [mean difference: -0.14 (95%CI: -1.34, 1.08), p=0.826] and 6-months [mean difference: -0.60 (95%CI: -1.82, 0.62), p=0.331] between intervention and comparison groups.

4.6.2.2.2 Between-subject Effects for Anxiety score

Table 4.37 shows the comparison of the mean anxiety score level between the intervention and comparison groups for between-subject effects for the interaction between time and group.

Table 4.29: Comparison of Anxiety scores between two study groups.

	Time	**Intervention** (n=77) Mean (SD)	**Comparison** (n=78) Mean (SD)	**F stat** (df)[a]	**p-value**[a]	**Partial effect size**, (partial η^2)
Time * Group	Baseline	6.02 (3.56)	5.56 (4,12)	19.790 (1,153)	<0.001*	0.157
	4-months	5.42 (3.71)	5.57 (3.92)			
	6-months	4.96 (3.76)	5.56 (3.91)			

[a] Repeated Measure ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the score of Anxiety (2 repeated measurements) between two study groups]
[b] p-values are adjusted for multiple comparison using Bonferroni procedure
* denotes statistically significant at α=0.05
df: degree of freedom; CI: confidence intervals

There was a significant difference in the anxiety score (3 repeated measurements) between intervention and comparison group ($p<0.001$). It indicated that the intervention group had significantly decreased anxiety scores compared to the comparison group. The effect size was small (15.7 percent).

4.6.2.2.3 Within-subject Effects for Anxiety Score

Table 4.38 shows the paired differences for mean anxiety scores from baseline to 4-months, baseline to 6-months and 4-months to 6-months in intervention and comparison groups.

Table 4.30: Paired differences for mean anxiety score from baseline to 4-month, baseline to 6-month and 4-month to 6-month in intervention and comparison groups

	Intervention (n=77)			**Comparison** (n=78)		
	t (df)	**Paired difference** (95%CI)	**p-value**	**t (df)**	**Paired difference** (95%CI)	**p-value**
Baseline vs 4-months	5.689 (76)	-0.60 (-0.81, -0.39)	<0.001*	0.001 (77)	0.01 (-0.19, 0.19)	0.999
Baseline vs 6-months	7.296 (76)	-1.06 (-1.36, -0.77)	<0.001*	0.002 (77)	0.01 (-0.15, 0.13)	0.989
4-month vs 6-months	4.815 (76)	-0.46 (-0.66, -0.27)	<0.001*	0.001 (77)	0.01 (-0.02, 0.06)	0.997

* statistically significant at $\alpha=0.05$
Statistical test: independent t-test

In the intervention group, there were significant paired mean differences from baseline to 4-months, baseline to 6-months and from 4-months to 6-months

throughout the study period. Meanwhile, there were no significant paired mean differences in the comparison group throughout the study period.

4.6.2.2.4 Post-hoc Multiple Comparison for Score of Anxiety

There was a significant interaction between time and group for within-subject effect [$F(2,306)=28.440$, $p<0.001$, partial $\eta^2=0.157$]. It indicated that the anxiety score for the intervention group decreased significantly compared to comparison group and the effect size was 15.7 percent.

Table 4.39 shows the post-hoc comparison of score of anxiety using Bonferroni procedure between intervention and comparison groups for anxiety (Interaction between Time and group).

Table 4.31: Post-hoc comparison of score of Anxiety (Interaction between Time and group) between two study groups at each pair of time level

Level		**F stat** (df)[a]	**Mean difference** (95%CI)	**p-value**[a,b]	**Partial effect size**, (partial η^2)
Time * Group	Baseline to 4-months	17.556 (1,153)	-0.30 (-0.44, -0.16)	<0.001*	0.103
	4-months to 6-months	23.490 (1,153)	-0.23 (-0.33, -0.14)	<0.001*	0.133

[a] Repeated Measure ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the score of MCS (2 repeated measurements) between two study groups]
[b] p-values are adjusted for multiple comparison using Bonferroni procedure
* denotes statistically significant at α=0.05
df: degree of freedom; CI: confidence intervals

There was a significant mean difference for anxiety score from baseline to 4-months ($p<0.001$). The mean difference for the anxiety score of the intervention group was significantly lower compared to the mean difference in the comparison group for the same time period. The effect size from baseline to 4-month was small (10.3 percent).

There was also a significant mean difference for anxiety score in the intervention and comparison group from 4-months to 6-months ($p<0.001$). The mean difference for the anxiety score of the intervention group was significantly lower than the comparison group. The effect size from 4-months to 6-months was also small (13.3 percent).

4.6.2.2.5 Within-subject Contrast for Anxiety

The within-subject contrasts for total anxiety score (Interaction between Time and group) and anxiety score (Interaction Time and Group adjusted by Metastases status) are shown in Table 4.40.

Table 4.32: Within-subject contrast for anxiety

	Trend	**F (df)**	**p-value**	**Partial effect size**, (partial η^2)
Time * Group	Linear	18,723 (1,153)	<0.001*	0.256
	Quadratic	2.867 (1,153)	0.100	0.001

* statistically significant at α=0.05
df: degree of freedom
Statistical test: Repeated Measure ANOVA (Time & Group Interaction Effect)

There were significant linear trends over time in the interaction of between time and group (intervention and comparison). The effect sizes accounted for linear trends in time and in the interaction of time and group in anxiety were small (25.6 percent). It was concluded that APMRT shows a relatively small effect in linear trend in time and in an interaction between time and group in decreasing anxiety score.

4.6.2.3 Stress

4.6.2.3.1 Mean Score of Stress throughout the Study

Figure 4.11 shows the mean score of stress for the intervention and comparison groups. For the intervention group, the mean stress score decreased modestly from baseline to 4-months as well as from 4-months to 6-months. For the comparison group, the mean stress score increased slightly from baseline to 4-months and from 4-months to 6-months.

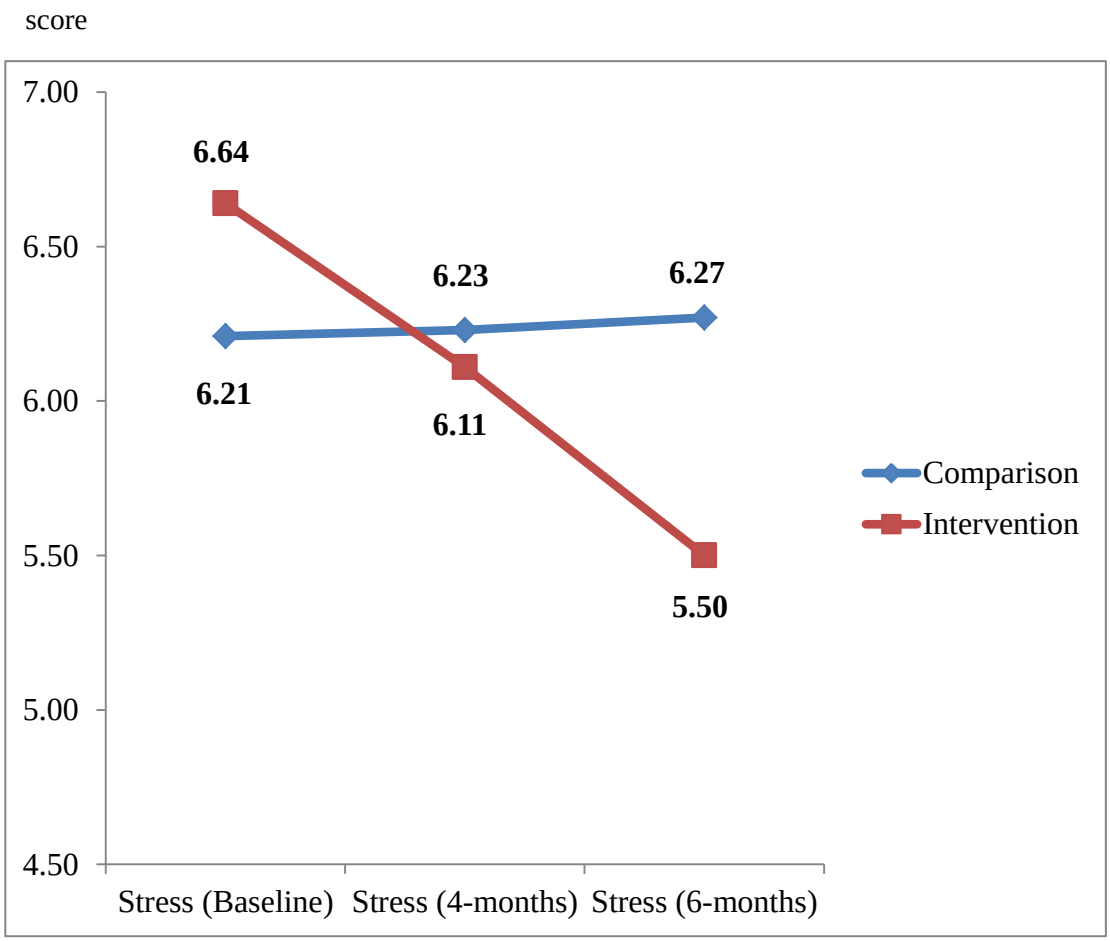


Figure 4.11: Stress score for both intervention and comparison groups

There were no significant differences in the mean stress scores at baseline [mean difference: 0.44 (95%CI: -1.28, 2.17), p=0.612], 4-months [mean difference: -0.07 (95%CI: -1.74, 1.59), p=0.930] and 6-months [mean difference: -0.72 (95%CI: -2.25, 0.81), p=0.353].

4.6.2.3.2 Between-subject Effects for Stress score

Table 4.41 shows the comparison of the mean stress score level between the intervention and comparison groups for between-subject effects for the interaction between time and group.

Table 4.33: Comparison of Stress scores between two study groups.

	Time	Intervention (n=77) Mean (SD)	Comparison (n=78) Mean (SD)	F stat (df)[a]	p-value[a]	Partial effect size, (partial η^2)
Time * Group	Baseline	6.64 (5.89)	6.20 (4.94)	9.931 (1,153)	<0.001*	0.116
	4-months	6.15 (5.54)	6.23 (4.92)			
	6-months	5.51 (4.74)	6.21 (4.94)			

[a] Repeated measures ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the pattern of Stress (3 repeated measurements) between two study groups]
* statistically significant at α=0.05
SD: standard deviation; df: degree of freedom

There was a significant difference in stress score (3 repeated measurements) between the intervention and comparison group ($p<0.001$). It indicated that the stress score of intervention group decreased significantly compared to the comparison group. The effect size accounted for stress score was small (11.6 percent).

4.6.2.3.3 Within-subject Effects for Stress Score

Table 4.42 shows paired differences for mean stress score from baseline to 4-months, baseline to 6-months and 4-months to 6-months in the intervention and comparison groups.

Table 4.34: Paired differences for mean stress score from baseline to 4-month, baseline to 6-month and 4-month to 6-month in intervention and comparison groups

Time	**Intervention** (n=77)			**Comparison** (n=78)		
	t (df)	**Paired difference** (95%CI)	**p-value**	**t (df)**	**Paired difference** (95%CI)	**p-value**
Baseline vs 4-months	4.674 (76)	-0.49 (-0.70, -0.28)	<0.001*	-0.331 (76)	-0.03 (-0.18, 0.13)	0.741
Baseline vs 6-months	4.690 (76)	-1.14 (-1.63, -0.66)	<0.001*	0.001 (0.77)	0.01 (-0.16, 0.16)	1.000
4-month vs 6-months	3.793 (76)	-0.65 (-0.99, -0.31)	<0.001*	1.000 (77)	0.03 (-0.03, 0.08)	0.320

* statistically significant at $\alpha=0.05$
CI: confidence intervals
Statistical test: independent t-test

In the intervention group, there were significant paired differences in the mean stress score throughout the study period. However, there were no significant paired differenced in the mean stress throughout the study period in comparison group.

There were significant decreases in stress score throughout the study period in the intervention group. There was slight increase in stress score from baseline to 4-months and baseline to 6-months among the comparison group.

4.6.2.3.4 Post-hoc Multiple Comparison for Score of Stress

There was significant interaction between time and group for within-subject effect [$F(1.211,164.631)=22.209$, $p<0.001$, partial $\eta^2=0.140$]. It indicated that the intervention group had significantly decreased stress score compared to the comparison group and the effect size was small (14.0 percent).

Table 4.43 shows the post-hoc comparison of score of stress using Bonferroni procedure between intervention and comparison groups for stress (Interaction between Time and group).

Table 4.35: Post-hoc comparison of score of Stress (Interaction between Time and group) between two study groups at each pair of time level.

Level		**F stat** (df)[a]	**Mean difference** (95%CI)	**p-value**[a,b]	**Partial effect size**, (partial η^2)
Time * Group	Baseline to 4-months	12.824 (1,153)	-0.22 (-0.36, -0.06)	<0.001*	0.077
	4-months to 6-months	15.393 (1,153)	-0.34 (-0.51, -0.17)	<0.001*	0.091

[a] Repeated Measure ANOVA (Time & Group Interaction Effect)
[Ho: There is no difference in the score of Stress (2 repeated measurements) between two study groups]
[b] p-values are adjusted for multiple comparison using Bonferroni procedure
* denotes statistically significant at α=0.05
df: degree of freedom; CI: confidence intervals

There was a significant mean difference for stress score from baseline to 4-months (p=0.001). The mean difference of the stress score for the intervention group was significantly lower compared to the comparison group. The effect size accounted for anxiety score from baseline to 4-months was small (7.7 percent).

There was also a significant mean difference of stress score from 4-months to 6-months (p<0.001). The stress score of the intervention group was significantly lower compared to the comparison group. The effect size from 4-months to 6-months was also small (9.1 percent).

4.6.2.2.4 Within-subject Contrasts for Stress

The within-subject contrasts for total stress score is shown in Table 4.44.

Table 4.36: Within-subject contrast for stress

	Trend	**F (df)**	**p-value**	**Partial effect size**, (partial η^2)
Time * Group	Linear	19.987 (1,153)	<0.001*	0.116
	Quadratic	0.071 (1,153)	0.108	0.016

* statistically significant at α=0.05
df: degree of freedom

There were significant linear trends over time in the interaction of between time and group (intervention and comparison). The effect sizes accounted for linear trends in time and in the interaction of time and group in stress were small (11.6 percent). It

was concluded that APMRT shows a relatively small effect in linear trend in time and in an interaction between time and group in decreasing stress score.

4.6.2.4 Categories of Self-perceived Depression, Anxiety and Stress of the participants at baseline and 6-month of the Study

Categories of self-perceived depression, anxiety and stress among the patients at baseline and 6-months are shown in Table 4.45. There were no significant differences in the categories of self-perceived depression, anxiety and stress between intervention and comparison groups over the 6-months study period.

Table 4.37: Categories of Self-perceived Depression, Anxiety and Stress of the participants at baseline and 6-month of the Study.

	Classifi-cation	**Intervention** (n=77)				**Comparison** (n=78)			
		at baseline, Frequency (%)	**at 6-month**, Frequency (%)	**Chi-square** (df)	**p-value**	**at baseline**, Frequency (%)	**at 6-month**, Frequency (%)	**Chi-square** (df)	**p-value**
Depression	Normal	67 (87.0)	67 (87.0)	1.111	0.774#	64 (82.1)	63 (80.8)	0.061	0.970*
	Mild	5 (6.5)	5 (6.5)	(3)		9 (11.5)	10 (12.8)	(2)	
	Moderate	4 (5.2)	5 (6.5)			5 (6.4)	5 (6.4)		
	Severe	1 (1.3)	0 (0.0)			0 (0.0)	0 (0.0)		
Anxiety	Normal	55 (71.4)	57 (74.0)	1.010	0.799#	51 (65.4)	50 (64.1)	0.183	0.980#
	Mild	7 (9.1)	9 (11.7)	(3)		15 (19.2)	17 (21.8)	(3)	
	Moderate	13 (16.9)	10 (13.0)			11 (14.1)	10 (12.8)		
	Severe	2 (2.6)	1 (1.3)			1 (1.3)	1 (1.3)		
Stress	Normal	71 (92.2)	73 (94.8)	4.694	0.196#	74 (94.9)	73 (93.6)	0.150	0.928#
	Mild	2 (2.6)	4 (5.2)	(3)		3 (3.8)	4 (5.1)	(2)	
	Moderate	2 (2.6)	0 (0.0)			1 (1.3)	1 (1.3)		
	Severe	2 (2.6)	0 (0.0)			0 (0.0)	0 (0.0)		

Statistical test: #Fisher exact's test; *chi-square test

CHAPTER 5: DISCUSSION

This quasi-experimental study was carried out at University Malaya Medical Centre (UMMC) and Universiti Kebangsaan Malaysia Medical Centre (UKMMC) to determine the impact of applied progressive muscle relaxation training (APMRT) on depression, anxiety, stress and health related quality of life (HRQOL) among prostate cancer patients. All the participants were carefully assessed at the start of the study to confirm their diagnosis as prostate cancer and to exclude them when they had any of the exclusion criteria.

Due to very little resources and time limitation, quasi-experimental study was the best study design conducted in this study. However, quasi-experimental study has many limitations such as: (i) it may provide weaker evidence because of the lack of randomness. Randomness brings a lot of useful information to a study because it broadens results and therefore gives a better representation of the population as a whole; and (ii) using unequal groups in this study can also be a threat to internal validity.

Since there is no randomization, the conclusions about causal relationships are difficult to determine due to a variety of extraneous and confounding variables that exist in a social environment. Moreover, even if these threats to internal validity are assessed, causation still cannot be fully established because the experimenter does not have total control overextraneous variables.

The intervention group was given three one-hour sessions of AMPRT before they self-practiced at home guided by a compact disc containing the APMRT instruction. Each session contained six modules to complete. All the participants were followed-up for six months. The mechanism of APMRT may help the investigators and clinicians decide whether APMRT is indicated for psychological problems and improvement for quality of life among prostate cancer patients.

5.1 Instruments used in assessment

There were two self-administered questionnaires used in the assessment. There were Short Form Health Survey the RAND-36 General Health Related Quality of Life (SF-36) and Depression, Anxiety, Stress Scale – 21 (DASS-21).

5.1.1 Depression, Anxiety, Stress Scale – 21 (DASS-21)

The DASS-21 was chosen for this study. The reasons of choosing DASS-21were: its subscales assess the three psychological problems which where depression, anxiety and stress (Lovibond & Lovibond, 1995a). It contained only 21 questionnaires so that only a few minutes were required to finish the assessment. The original DASS-21 had higher Cronbach's alpha and internal consistency. The Malay language of DASS-21 has been translated (Musa et al., 2007) and demonstrated good concurrent and criterion-related validity (Musa et al., 2009). It also can be used to measure the dimension of depression, anxiety and stress among clinical sample (Brown et al., 1997; Gloster et al., 2008; Musa et al., 2009)

5.1.2 Short Form Health Survey the RAND-36 General Health Related Quality of Life (SF-36)

In this study, the general health related quality of life (HRQOL) was assessed using Short Form Health Survey SF-36 (Hays & Morales, 2001). The reasons of choosing SF-36 were: (i) It is a generic measure to assess the health status since this study did not target the cancer specific or disease specific measures, (ii) the SF-36 has been shown to be reliable and valid (Ware et al., 1998; Ware et al., 1993), (iii) it is also valid instrument for an older people (Walters et al., 2001) and (iv) the original SF-36 demonstrated high internal consistency 91 (Ware et al., 1998) and the Malay language also demonstrated the same result (Abu Bakar et al., 2003)

5.2 Reliability Analysis of the Instruments

5.2.1 Reliability Analysis for DASS-21

The internal consistency for DASS-21 was more than 0.70. It indicated that DASS-21 had high reliability according to Hinton et al., (2004) criteria . The reliability of DASS subscales in this study population was lower compared to among patients with phobia and anxiety (Brown et al., 1997), among diabetes patients (Musa et al., 2009), medical patients (Gloster et al., 2008), employee absent from work (Nieuwenhuijsen, de-Boer, Verbeek, Blonk, & van-Djik, 2003), general adult population (Crawford & Henry, 2003) and psychology students (Bados et al., 2005).

The Cronbach's alpha was lower in this study. It could be due to less inter-relatedness between items and less heterogeneous construct (Tavakol & Dennick, 2011). However, the Cronbach's alpha was in the acceptable values (Tavakol &

Dennick, 2011). It can be concluded that DASS-21 showed good psychometric properties in this study.

5.2.2 Reliability Analysis for SF-36

The Cronbach's α for SF-36 was more than 0.70 and was within the acceptable range of instrument standardization (Ware et al., 1993). It indicated that SF-36 had a high reliability according to Hinton et al., (2004) criteria. However, the reliability of SF-36 in this study was lower compared to community-based survey among older adults in Sheffield, UK (Walters et al., 2001), older people in HALCyon study program in UK (Mishra et al., 2011), elderly people in Korea (Han, Lee, Iwaya, Kataoka, & Kohzuki, 2004) and elderly Iranian population (Eshaghi, Ramezani, Shahsanaee, & Pooya, 2006).

This could be due to less inter-relatedness between item and less heterogeneous construct (Tavakol & Dennick, 2011). Although the value of Cronbach's α was lower compared to other study, the psychometric properties of the SF-36 were suitable for this study population.

5.3 Baseline Characteristics of Patients

5.3.1 Socio-demographic Characteristic of Patients

The majority of the prostate cancer patients in this study were more than 70 years old which was similar with the age group reported by the National Cancer Registry of Malaysia for prostate cancer patients (Gerard Lim et al., 2008; Gerard Lim et al., 2003; Gerard Lim & Yahya, 2004; Omar & Ibrahim-Tamin, 2011), studies in

Universiti Kebangsaan Malaysia Medical Centre (UKMMC) (Subair et al., 2009) and Gaza City (Abu El Noor, 2010)**.** In the seven-year observation of TRUS biopsy conducted in UKMMC, the median age at diagnosis of prostate cancer was slightly lower and more than 50 percent were diagnosed before the age of 70 (Goh et al., 2010). The observations that the proportion of prostate cancer was lower in age group more than 80 years old compared to age 70 to 79 years old could be due to "under-screening" and "under-diagnosis" of this cancer (Harding, Pompei, Lee, & Wilson, 2008). For example, the US Preventive Services Task Force does not recommend performing PSA tests for men aged more than 75 years old (Harris & Lohr, 2008).

Physiologically, when men become older, the prostate gland is the most pathologically transformed organ (Grover & Martin, 2002). One theory suggested that in every mother cell that gives rise to two daughter cells there is alteration in its DNA which consequently affects the RNA and protein translation. The protein alteration may be even further altered, thus giving rise to malignancies (Mydlo, 2003). In Malaysia, prostate cancer is frequently diagnosed very late (Goh et al., 2010).

Chinese formed the highest proportions in our study. This demographic characteristics was similar as found in the previous three reports in the National Cancer Registry, Malaysia for prostate cancer (Gerard Lim et al., 2008; Gerard Lim et al., 2003; Omar & Ibrahim-Tamin, 2011) and two studies in UKMMC (Goh et al., 2010; Subair et al., 2009). However, in the Second Report of the National Cancer Registry in 2003, Indian was the largest ethnic group for prostate cancer cases

(Gerard Lim & Yahya, 2004). It could be the de-duplication problem while reporting the data and the process of assigning one value for the variables when reported values that conflict with each other. The highest proportion of prostate cancer in certain races could be due to genetic susceptibility or ethnic polymorphisms related to androgen metabolism (Cussenot, 2004).

Majority of patients in both groups were married and stayed with their family members which were similarly found in the study reported by Abu-El-Noor (2010). Married patients were found to have longer survival when compared to non-married patients (Krongrad et al., 1996). However, patients with higher number of marriages was found to be at higher risk for prostate cancer compared to never married (Vecchia et al., 1993).

5.3.2 History of chronic diseases of the patients

In Malaysia, chronic diseases accounted 71 percent of all deaths in 2002 (World Health Organization, 2005). In our study, almost 90 percent of participants also had other co-morbidity besides prostate cancer. The proportion with other co-morbidities was higher in this study population compared to the report from NHMS III (45.8 percent) (Ministry of Health Malaysia, 2008) and elderly population in Selangor (57.4 percent) (Mohd Sidik, Mohd Zulkefli, & Mustaqim, 2003a). Since the study participants were selected from hospital based population hence it is not surprising that the proportion of co-morbidities was significantly higher compared to the study in the community.

In our study, hypertension was the most common chronic disease among the participants. This is similar with the report from NHMS III regarding chronic diseases (Ministry of Health Malaysia, 2008). Rampal et al., (2008) reported that men aged more than 60 years old had significant higher prevalence with hypertension [adjusted odd ratio: 22.5]. The percentage of hypertension in our study was higher compared to the report from NHMS III (Ministry of Health Malaysia, 2008) and two other surveys conducted at the national level (Ho, Jasvinder, Balkish, & Azahadi, 2011; Rampal et al., 2008). The higher proportion in our study could be due to the fact that our participants were clinical sample rather than general population from community. The percentage of hypertension was lower in two local rural community studies compared to our finding (Cheah, Lee, Yaman, & Abdul-Wahab, 2011; Mohd Yunus, Sherina, Nor Afiah, Rampal, & Tiew, 2004).

The proportion of diabetes mellitus in our study was almost similar with the study conducted by Abu-El-Noor (2010) among prostate cancer patients in Gaza City. However, our study found higher percentage in diabetes mellitus than NHMS III report in 2006 among elderly people (Letchuman et al., 2010). Diabetes mellitus ranked sixth (2.9 percent) which was among top ten causes of disability adjusted life years (DALYs) in Malaysia (Faudzi et al., 2004). This higher percentage could be due to the positive link between diabetes status and prostate cancer, mostly in men age 40 – 64 years old (Tseng, 2011). However, a prospective cohort study by Rodriguez et al., (2005) found that patients with diabetes had reduced incidence of prostate cancer at the time of diagnosis for diabetes but increased in incidence after the diagnosis of diabetes mellitus.

In our study, the proportion of hypercholesterolemia was higher compared to the NHMS III report in 2006 (Ministry of Health Malaysia, 2008). The prevalence of hypercholesterolemia was positively associated with age, female sex, family history of hypercholesterolemia and low levels of attained education (Ministry of Health Malaysia, 2008). Tseng (2011) also found that hypercholesterolemia was one of the risk factor for prostate cancer.

The Malaysian Burden of Disease and Injury Study in year 2000 found that ischaemic heart disease ranked first (10.0 percent) among the top ten causes of disability adjusted life years (DALYs) among men in Malaysia (Faudzi et al., 2004). The coronary artery disease was significantly associated with a 35 percent increase in prostate cancer diagnosis (Thomas et al., 2012). The percentage of heart disease in our study was higher compared to the report from NHMS III (Ministry of Health Malaysia, 2008). Heart disease has been associated with an increased risk for prostate cancer (Tseng, 2011).

Hypertension, hyperglycaemia and hypercholesterolemia are modifiable risk factors for chronic diseases that can be prevented through lifestyles changes (Ministry of Health Malaysia, 2003). Health interventions need to be carried out to ensure that the public acquire the necessary knowledge to prevent these chronic diseases (Cheah et al., 2011).

5.3.3 Lifestyle practices of the patients – smoking, alcohol and sexual statuses

More than 50 percent of patients in both groups were smokers and the result was almost similar in the study conducted by Subair et al., (2009) in UKMMC. However,

the proportion of ever smoking was higher compared with NHMS III in year 2006 among men aged 50 years old and above (Ministry of Health Malaysia, 2008). New evidences found that smoking can encourage tumour growth in prostate cancer patients (Fradet et al., 2009) and is associated with a significant increase in risk of prostate cancer-specific mortality (Gong, Agalliu, Lin, Stanford, & Kristal, 2008).

Almost one third of our patients ever consumed alcohol and the proportion were also higher compared to the prevalence of ever consuming alcohol in NHMS III in year 2006 (Ministry of Health Malaysia, 2008). Higher alcohol consumption modestly increased non-advanced prostate cancer risk. The risk was 25 percent higher for men consuming more than 6 drinks daily (hazard ratio = 1.25) and for those consuming three to six drinks daily had increased risk of 19 percent compared to non-drinker (Watters, Park, Hollenbeck, Schatzkin, & Albanes, 2010). Reduction of the alcohol beverages intake is recommended to improve the management of patients with urologic disease including cancer (Mydlo, 2003).

Less than 10 percent of our patients were sexually active. However, the proportion was higher compared to study conducted by Subair et al., (2009) in UKMMC. The low proportion could be due to old age and some of them having erectile dysfunction. Having sex is not contradicted in prostate cancer. However, patients who had radical prostatectomy, they need to avoid to have sex for the first six to eight week after the surgery (Cancer Research UK, 2010). They were encouraged to use condom for the first time they had sex after treatment. The patients who fail initial measures to restore normal sexual function should not defer from seeking help for sexual rehabilitation. Both patients and partner require proper counselling to

address the physical and psychological issues involved with the sexual dysfunction in their relationship (McCullough, Ginsberg, & Harkaway, 2003). It has been hypothesized that increased in sexual activity imparted a protective effect against the development of prostate cancer (Harvei & Kravdal, 1997).

5.3.4 Current urinary complaints of the patients

There are no specific symptoms for prostate cancer during its early development phase (Bardan et al., 2007). However, local advanced disease is more likely to have an increase in LUTS and in case of metastatic prostate cancer, patients may present with lumbar or pelvic pain (Bracarda et al., 2005). In this study, nocturia was the most common current urinary complaint in both groups. Other urinary complaints were frequency, intermittency, incomplete emptying, urgency, dysuria, hematuria and straining. During a Prostate Awareness Campaigns in 2005 in Malaysia, nocturia was also found to be the most bothersome symptom among males over 50 years old (Sothilingam, Sundram, Malek, & Sahabuddin, 2010).

Treating urinary problem is very important in patients with prostate cancer. Practising pelvic floor or sphincter exercises may help to speed up the return of urine control among prostate cancer patients (Irish Cancer Society, 2012). Even though our patients had at least one urinary complaint, more than 50 percent of them were satisfied with their current micturition.

5.3.5 Current cancer status of the patients

About 25 percent of our study population have had prostate cancer for more than 5 years. The good survival rate could be due to good medical care after prostate cancer patients were diagnosed (Sim & Cheng, 2005). Living with prostate cancer may have physical and emotional impact on their life and their spouses. Even when treatment is discontinued, they may face side effects of the treatment (The Prostate Cancer Charity, 2011).

In a seven-year review of prostate cancer diagnosed by TRUS biopsy in UKMMC, the median PSA level found at time of diagnosis was 574 ng/mL (range 1 – 8632) (Goh et al., 2010). Similar level of PSA was also found in our study. Several multi centric trials, found the diagnosis rate for prostate cancer was proportional with PSA level (Bunting, 2002; Frankel et al., 2003). PSA measurement should be monitored in population at risk but the merits and limitations of this assay should be explained to the patients (Lai et al., 2003).

Monitoring the level of PSA can avoid unnecessary side effects that could affect patients' quality of life (Cancer Research UK, 2010). There is no consensus what should be the target value (American Family Physician, 2000). However, the cut-off 4mg/mL is always used by the urologist for further management of prostate cancer (American Urological Association, 2000). In our study, about 60 percent of the patients had PSA less than 4mg/mL. PSA less than 0.5ng/mL (or undetectable levels) is not likely to be associated with recurrence of the disease within five years of treatment for prostate cancer (American Family Physician, 2000). However, prospective study by Litchfield et al., (2012) found the PSA level increased from 7.5

percent among men aged 70 – 74 years to 31.4 percent among men aged more than 90 years.

Gleason score evaluates the glandular histology of the prostate gland, the pattern of the growth of the tumour and the relationship between the tumour cells and the surrounding tissue (Bardan et al., 2007). The lower grade of Gleason score suggest a well differentiated tumour (Bracarda et al., 2005). The result from our study was the same with the study by Prostate Cancer Research Institute which involved 54,000 participants (O'Dowd, Veltri, Miller, & Strum, 2001). However, in the TRUS biopsy study done in UKMMC from 2002 to 2008 found slightly higher Gleason score (Goh et al., 2010). So that, the urologist should consider the overall likelihood of tumour in our patients as well as specific characteristics, such as prostatic specific antigen and the percent of tumor in the prostate biopsy when contemplating treatment such as watchful waiting or brachytherapy (Pinthus et al., 2006).

Metastases is reported when there is a distant metastases of tumour outside the prostate gland and it can be to the non-regional lymph nodes, bone and other site(s) with or without bone disease (Bracarda et al., 2005). Lymph node metastases are frequent among patients with large, poorly differentiated tumour or in cases of early invasion of the seminal vesicles (Bardan et al., 2007). In this study, more than 50.0 percent of the patients had metastases. It can be concluded that the prostate cancer of more than half of our patients had spread to other parts of the body. The most common site of metastases was bone (Goh et al., 2010). Our study could not report the site of metastases due to unavailable information or missing data. Half of our

patients were at risk of pain, fracture, spinal cord compression and hypercalcemia due to metastases.

Adenocarcinoma accounted around 95 percent in prostate cancers (American Cancer Society, 2011; Bracarda et al., 2005). Adenocarcinoma was the only type of cancer reported in both groups of patients in our study, similar with the report from Cancer Incidence in Peninsular Malaysia 2003 – 2005 (Gerard Lim et al., 2008).

Family history is an important risk factor for prostate cancer (Bardan et al., 2007). About 25.0 percent of our participants had family history of prostate cancer. Family history data provides evidence for the genetic component in prostate cancer aetiology (Cussenot, 2004). Inherited genetic factors contributed to 42 percent of prostate cancer risk (Lichtenstein et al., 2000). The risk of acquiring prostate cancer was found to be much higher when the prostate cancer was diagnosed among fathers before the age of 70 years old than when it was diagnosed after 70 years old (Cussenot, 2004).

5.3.6 Treatment for prostate cancer

Treatment given for prostate cancer patients was based on the initial PSA, stage and grade of the disease, prognostic feature of the cancer, patients' age, general conditions of the patients and patients' preference (Bracarda et al., 2005; Malaysian Urological Association, 2006; Whelan, 2008). Surgery, watchful waiting and radiotherapy (with and without hormone-therapy) are the appropriate choices for patients with localized disease. Hormonal therapy plus radiotherapy is appropriate

for locally advanced disease (Bracarda et al., 2005) and multidisciplinary effort in cancer care is essential in metastasis and advanced disease (Gerard Lim, 2002).

In our study, hormonal therapy was the most common treatment given (more than 80 percent). The proportion of zoladex injection was significantly higher in the comparison group while lucrine injection was significantly higher in the intervention group. The decision of giving LHRH agonis depended on the urologist and oncologist. Although a significant difference found in the treatment given in both groups, zoladex and lucrine were in the same group of LHRH agonist.

However, our finding contradicted with the results shown by Abu El Noor (2010). A hormonal treatment was used for symptomatic patients with advanced disease (Whelan, 2008). In the seven-year review of prostate cancer in UKMMC, hormonal manipulation was also the commonest prescribed treatment for prostate cancer patients seen at that facility (Goh et al., 2010). Since hormonal therapy was the commonest treatment in our study, our patients may face side effects such as hot flushes, pain over the bone, joints and testis, swelling or tenderness of the breast, loss of libido, weight gain and weakness. Long term hormonal therapy may decrease bone density that lead to osteoporosis (Baker et al., 2008; Welch & Albertsen, 2009).

5.4 Health-Related Quality of Life

5.4.1 Total quality of life (QOL)

The primary end points in most cancer research are survival and quality of life. Certainly, the quality of life issues should always be taken into account during counselling sessions with newly diagnosed prostate cancer patients (Davis &

Schellhammer, 2003). The overall quality of life in this study population was above the average according to Ware (2000) criteria. The mean score in this study was higher than that the study found in Gaza by Abu-El-Noor (2010). In the Gaza study, it is due to factors related to availability, organizational, geographical, socio-economic and barriers related directly to the blockage imposed on Gaza City.

Mental health domain achieved the highest score in our study. Study by Abu-El-Noor (2010) also found bodily pain domain was the highest and while other studies found social functioning domain was the highest (Albertsen, Aaronson, Muller, Keller, & Ware, 1997; Litwin et al., 1998). The lowest mean score in our study was the role of physical domain, similar to findings presented elsewhere (Albertsen et al., 1997; Jayadevappa et al., 2006; Litwin et al., 1998).

The quality of life of patients depends on type of treatment received. There is no treatment that is better or worse and each treatment has its own unique impact on quality of life. No treatment can completely avoid the risk of serious side effects. In the first two years after treatment, the side effect tend to diminish or become less serious (Litwin et al., 2007).

5.4.2 Comparison between Physical Component Summary (PCS) and Mental Component Summary (MCS)

The physical component summary (PCS) and mental component summary (MCS) were derived from the eight domains. The PCS was strongly correlated with physical function, role physical, bodily pain, vitality and social function. Meanwhile, MCS was strongly correlated with mental health, role emotional, social functions, vitality

and social function (Ware et al., 1998). On average the population in our study found no physical limitations and disabilities or decrements in well-being. They had a high energy level and "excellent health rated" (Ware, 2000). The patients also had an average positive effect, absence of psychological distress and limitations in usual social/role activities due to emotional problem (Ware, 2000).

The score of PCS was lower compared to MCS in our study and this result was consistent with other studies (Cleary et al., 1995; Litwin et al., 1998; Namiki & Arai, 2010; Penson et al., 2003b). However, Abu-El-Noor (2003) found PCS score was higher compared to the MCS score. None of prostate cancer patients in our study were found to have limitation in self-care, physical, social and role activities, severe body pain and frequent tiredness. There were no patients having frequent psychological distress, social and role disability due to emotional problems.

It was observed that a relatively higher score in MCS compared to PCS among our patients indicated that mental health was less affected by prostate cancer. This could be due to our participants having better coping mechanism and adaptation to this chronic disease. Those who had radical prostatectomies were having false thinking that when the prostate gland removed, the cancer would not return to that organ again. Thus, those men did not worry about having prostate cancer in the future because they thought that the cancer had been permanently removed. Among radiation patients, they had slower physical recovery compared to those with prostatectomies. However, their mental health stayed the same over the 24 months (Litwin et al., 1995). This could be the other reason why physical health was lower than mental health among prostate cancer patients.

The different findings from other studies could be attributed to factors including utilization of the study instrument, selection, definition and sample size and the inherent cultural differences that exist between countries (Jayadevappa et al., 2006).

5.4.3 Correlation between Physical Component Summary (PCS) and Mental Component Summary (MCS)

In this study, there was a significant moderate positive correlation between PCS and MCS in both groups. This finding was similar among patients who receive medical care (Farivar, Cunningham, & Hays, 2007). However, Lubeck et al., (1997) found lower correlation compared to our study. In prostate cancer patients, when the mental condition remains stable, then they are in good physical condition (Niimi et al., 1997). According to the Canadian Mental Health Association (2003), the condition of mental health may weaken the immune system, therefore it increases the likelihood of developing physical illness.

5.4.4 Correlation between Age and Health Related Quality of Life (HRQOL)

There was a significant negative weak correlation between age and quality of life in our study. It indicated that as age increased, the quality of life decreased. This finding was similar with other studies that correlate between age and quality of life among prostate cancer patients (Eton et al., 2001; Ghafari et al., 2009; Hoffman et al., 2004; Penson et al., 1998; Zenger et al., 2010). The study conducted by Schag et al., (1994) also concluded that quality of life of prostate cancer patients decreased slowly with time.

Ghafari et al., (2009) found a weak negative correlation between mental component summary and age; and between physical component summary and age. Both of these results concur with the finding in our study. Ghafari et al., (2009) concluded that the reasons of weak negative correlation were due the chronic nature of multiple sclerosis and the pathophysiological changes associated with ageing that lead to lowering of patient's quality of life. It can be the same reason in our population.

In old age, urinary incontinence and sexual function were age-related and independently associated with co-morbidity (Pinkawa et al., 2009). Since HRQOL declined with time, greater efforts should be made to understand the rehabilitation problems of this advanced disease so that the problems can be anticipated (Albertsen et al., 1997).

5.5 Depression, Anxiety and Stress

The DASS version 21 (DASS-21) questionnaire was used to assess the severity of self-perceived depression, anxiety and stress. DASS cut-off of ≥ 78 percentile scores was applied to determine significant depression, anxiety and stress (Lovibond & Lovibond, 1995a). The higher the score, the worse is the psychological condition.

In general, prostate cancer patients did not report higher level of psychological distress compared to general population due to a relatively good prognosis (Mehnert, Lehmann, Graefen, Huland, & Koch, 2010). The clinician may underestimate the psychiatric co-morbidity among prostate cancer patients and many of them had a few symptoms that were not diagnosed and hence may not receive any treatment

(Steginga et al., 2001). Early detection of psychiatric morbidity is needed in primary care and their determinants can help in psychiatric services planning for elderly and treating them (Latiffah, Nor-Afiah, & Shashikala, 2005). Similar principles can be applied to prostate cancer patients too.

5.5.1 Depression

5.5.1.1 The mean score of depression using DASS-21

The mean depression score in this study population was lower compared to the depression score among patients with stress and anxiety disorder (Brown et al., 1997), adjustment disorder patients (Nieuwenhuijsen et al., 2003) and male workers (Nordin, Abdin, & Naing, 2008). It could be due to depression among prostate cancer is harder to diagnose (Couper et al., 2006). Depression may be harder to diagnose in men with prostate cancer because common physical symptoms, such as feeling tired or losing weight may be attributed to prostate cancer or side-effects of its treatment, when in fact these could be signs of depression.

The physical symptoms such as losing weight and feeling tired may be attributed to prostate cancer treatment side effect, when in fact these could be signs of depression. Depression was found to be higher among workers who had job insecurity (Ferrie, Shipley, Newman, Stansfeld, & Marmot, 2005) and lack of supervisor support (Abdin et al., 2008).

The depression mean score in our finding was higher compared to the general adult population in UK (Henry & Crawford, 2005). Prostate cancer patients may have higher rate of depression than in the general population possibly due to the need of

outpatient and emergency visits or hospitalization among this patients (Hinz et al., 2009; Korfage et al., 2006).

5.5.1.2 The categories of depression

About 12 percent of our study populations were categorized as depressed. The result was higher compared to the study in Scotland (8.2 percent) (Walker et al., 2007). However, our finding was lower compared to the study by Nelson et al., (2009a) (14 percent), Sharpley & Christie (2007a) in Australia (16 percent) and Driksen et al. (2009) (51 percent). These variations could be due to different instruments used for depression assessment, type of study design, staging and treatment for prostate cancer.

The proportion of depression among our patients was higher compared to two local studies among elderly people (Mohd Sidik et al., 2003a; Mohd Sidik, Rampal, Aini, & Norhidayati, 2005) and among community in UK (Crawford & Henry, 2003; Walker et al., 2007). It is due to the need of outpatient and emergency visits or hospitalization in prostate cancer patient compared to general population (Hinz et al., 2009; Korfage et al., 2006). Higher proportion of depression among prostate cancer could be due to the side effect of the treatment that impacted their sleep performance (Dirksen et al., 2009). On the other hand, the percentage of depression in our study was lower than elderly patients in primary health care clinics (18.0 percent) (Mohd Sidik, Mohd Zulkefli, & Shah, 2003b) and among elderly warded in tertiary hospitals in Wilayah Persekutuan Kuala Lumpur (54.0 percent) (Mohd Sidik, Rampal, & Arfah Hanim, 2006).

Depressive symptoms remain an important concern and require greater attention for aging prostate cancer patients (Nelson et al., 2009a). Nelson et al., (2009a) found that aging was associated with greater depressive symptoms in prostate cancer patients (r=0.18).

A review done for 13 articles by Firdaus & Oei (2011) found that the prevalence of depression among Malaysian population ranged from 6.7 percent to 14.4 percent. The prevalence of depression among prostate cancer in our study was in the same range and it can be concluded that the depression was almost the same compared to Malaysian population.

5.5.2 Anxiety

5.5.2.1 The mean score of anxiety using DASS-21

Comparing with other studies using DASS for anxiety scoring, the DASS-Anxiety in this study population was higher compared to the anxiety score among general UK adult population (Crawford & Henry, 2003) and first year psychology students (Lovibond & Lovibond, 1995b). However, the anxiety score was lower compared to male automotive assembly workers (Abdin et al., 2008) and older primary care patients (Gloster et al., 2008).

5.5.2.2 The categories of anxiety

Our study found that 25.9 percent of prostate cancer patients reported self-perceived anxiety. This proportion is relatively high compared to the proportion among

prostate cancer in Australia (Sharpley & Christie, 2007a) and in the UK (Bission et al., 2002). It could be due to different measurement scale used in their anxiety assessment. The percentage of anxiety in this study was also higher compared to the general adult population in the UK (18.3 percent) (Crawford & Henry, 2003). Prostate cancer patients were more likely to suffer anxiety disorder than men in the general community (Couper et al., 2006; Hinz et al., 2009).

However, the proportion was lower than the male automotive assembly workers (52.9 percent) (Abdin et al., 2008). It could be due to high stress level associated with low back disorders over time among the assembly workers. Anxiety among prostate cancer was due to different factors surrounding diagnosis, treatment and remission. For example, concerning PSA levels, treatment and potential side-effects may compound the patients' anxiety (Sharpley et al., 2007)

5.5.3 Stress

5.5.3.1 The score of stress using DASS-21

The overall stress score using DASS-21 was 6.53. Based on the cut-off point for stress using DASS-21 (0 to 14 is normal) (Lovibond & Lovibond, 1995a), it can be considered that prostate cancer patients in this study were not stressed.

Comparing with other studies using DASS for the scoring of stress, our finding was lower compared to stress score among general UK adult population (Crawford & Henry, 2003), first year psychology students (Lovibond & Lovibond, 1995b), older primary care patients (Gloster et al., 2008) and among male automotive assembly workers (Abdin et al., 2008). Higher stress among male automotive workers could be

due to exposures to unsafe equipments, dirty or badly maintained areas, dealing with dangerous tools, machinery or equipment, fire, burn and shock (Abdin et al., 2008).

5.5.3.2 The categories of stress

The proportion of stress in this study was 5.7 percent which was almost similar with the findings among prostate cancer patients in the study using Danish Cancer Registry (Nielsen et al., 2007). However, our finding was lower compared to study by Hsiao (2008) in Arizona, US. The lower finding could be the different questionnaire used in the assessment.

There were many reasons why different questionnaire resulted in different prevalence rates of stress. It could be due to the different question sequence and structure. The order and presentation of questions can affect the quality of information gathered. The other reasons was the length of questionnaires. If the questionnaire is too lengthy, the patients will lose interest and either stop responding or respond hastily, inaccurately and without thought in order to bring the session to the end. The questionnaire layout can also be the reason since it can affect the efficiency of the study (Colin L. Soskolne & Stellman, 2011).

Compared to other populations, our finding was lower than the general adults in UK population (Crawford & Henry, 2003) and male automotive assembly workers (Abdin et al., 2008). There was no report of extremely severe stress among our participants. However, there was 2.0 percent in general adult UK population (Crawford & Henry, 2003) and 0.3 percent among male automotive assembly workers had been reported having extremely severe stress (Abdin et al., 2008). Low

levels of stress among prostate cancer was probable due to the nature of prostate cancer (Hsiao, 2008) and the patients ability to cope with the diagnosis and management of the disease (Wilkinson et al., 2008).

5.6 Process evaluation

Since this was a quasi-experimental study, it was important to maintain the completion rate to an acceptable level that could provide internal validity. The completion rate at 4-months was 92.2 percent and 91.0 percent in intervention and comparison groups respectively. Meanwhile, at 6-months, the completion rate was 90.9 percent and 87.2 percent in intervention and comparison groups respectively. The high response rate in this study could be related to the fact that participants were approached directly, either in person or by telephone, which provided participants with details about the purpose of the study and gave them a chance to answer their questions which encouraged hesitant participants to participate in the study.

The good completion rate was perhaps indicative of the patients' enthusiasm and appreciation of attention and treatments from the investigator. It was accepted that a response rate of 87.2 percent to 92.2 percent is sufficient for generalization (Burkell, 2003). It is suggested that the response rate can be improved by use of incentives and reminder letters (Edwards et al., 2002).

5.7 Outcome evaluation

We expected that APMRT would result in decreasing the scores of depression, anxiety and stress and increase in health related quality of life (HRQOL) score.

5.7.1 Outcome evaluation for Health Related Quality of Life (HRQOL)

HRQOL was assessed using Short Form Health Survey with 36 questionnaires (SF-36). Physical Component Summary (PCS) and Mental Component Summary (MCS) scroes were computed using QualityMatric software. Jaeschke et al., (1989) considered that the difference is 6.5 to 8.3 points between intervention and comparison groups is clinically significant.

5.7.1.1 Outcome evaluation for Physical Component Summary (PCS)

In the between-subject effect of the therapy, there was no significant difference in the PCS score between intervention and comparison groups (p=0.656).

For within-subject effect for PCS; in the intervention group, the PCS score increased significantly from baseline to 4-months and from 4-months to 6-months. However, for the comparison group, there were no significance differences in PCS from baseline to 4-months and from 4-months to 6-months. It can be concluded that the APMRT had slight improvement in PCS score but not strong enough to made a significant different improvement.

The post-hoc multiple comparison and within-subject contrast for PCS score cannot be explore more since in the between-subject effect analysis was not significant with and without metastases status adjustment.

Our result contradicted the findings of other studies, where Cheung et al., (2003) found significant improvement for physical health among patients after stomas. The

relaxation therapy also significantly improved the physical component of SF-8 among multiple sclerosis patients (Ghafari et al., 2009) and physical function among irritable bowel disease patients (Mackereth et al., 2009). This difference could be due to majority of the prostate cancer patients were old and they were physically ill rather than post stoma, multiple sclerosis and irritable bowel disease patients.

Stress management involving relaxation and coping skills, information about prostate cancer and radical prostatectomy was found to be more effective in the improvement of PCS for the long term effect (Parker et al., 2009).

Boyce et al., (2003) found that the combination between cognitive behaviour and relaxation therapies had significant changes over time for physical role and functioning. Dehdari et al., (2009) found that by adding progressive muscle relaxation to usual care as exercise training and daily life style education to usual care, improved physical functioning among post-operative coronary artery bypass graft (CABG) patients. The non-significant finding in our study could be due to increase physical disability among the study population since majority of prostate cancer patients were elderly patients which is also similar with the findings of the study conducted by Hass & Sakr (1997) and Kumar & Anderson (2002).

5.7.1.2 Outcome evaluation for Mental Component Summary (MCS)

There was a significant difference between intervention and comparison groups in MCS score. However, the effect size was small (23.6 percent) and the improvement was not clinically significant since the difference was less than six points between the two groups (Jaeschke et al., 1989).

For within-subject effect for MCS; in the intervention group, the MCS score increased significantly from baseline to 4-months and from 4-months to 6-months. For the comparison group, there was a significant decreased difference in the MCS from baseline to 4-months. However, there was no significant difference in the MCS score from 4-months to 6-months.

The post-hoc multiple comparison, it was found that the MCS improved from baseline to 4-months and from 4-months to 6-months. However, there was no clinically significance since the differences of the mean MCS score were less than 6.5 points in both time period (Jaeschke et al., 1989). The effect sizes at both time periods were also small (10.4 percent and 7.5 percent). It can be concluded that the APMRT had an advantage to improve the MCS score throughout the study period.

By looking the within-subject contrast, the APMRT improved the MCS score by linear trend although the effect size was small (25.2 percent). It can be concluded that the APMRT could achieve the clinically significant if the therapy given longer than six months.

Our results supported the findings of some previous studies that investigated the impact of different relaxation techniques on MCS score among multiple sclerosis patients (Ghafari et al., 2009; Mackereth et al., 2009) and community in Australia (Smith et al., 2007). Study by Smith et al., (2007) found that yoga was more effective in improving mental health for short and long term. Combination of yoga and APMRT can be suggested to the patients in order to get better outcome. Boyce et al., (2003) found that the combination of cognitive behaviour and relaxation therapy,

did not show any significant changes over time in the mental health ($p>0.05$) among patients with irritable bowel disease.

APMRT may work through the body and mind. The therapy relaxes both mind and body that improves concentration and mood. These activities cause the body to release chemical and brain signals that slow down the activities of muscle and organs and increases blood flow to the brain (Benson, 1975). During relaxation, the parasympathetic activities are promoted and blood pressure, heart rate, muscle tension, and rate of breathing are reduced as well as promoting calmness and being in control (Widmaier et al., 2006).

5.7.1.3 Outcome evaluation for Total Quality of Life (QOL)

In between-subject analysis on the impact of APMRT on the total QOL score, there was a significant difference between intervention and comparison groups. The total QOL score was higher in intervention group compared to comparison group However, the effect size was small (5.1 percent) and the improvement was not clinically significant since the difference was less than six points between the two groups (Jaeschke et al., 1989).

For within-subject effect; the total QOL score increased significantly from baseline to 4-months in the intervention group. However, there was no significant different in the total QOL from 4-months to 6-months. For the comparison group, there was no significant decreased difference in the total QOL from baseline to 4-months and from 4-months to 6-months. It can be concluded that the APMRT had an advantage to improve the total QOL within the short period of time.

The post-hoc multiple comparison, it was found that the total QOL improved from baseline to 4-months only and not from 4-months to 6-months. This supported the result that the impact of APMRT on total QOL was only within short period of time. However, there was no clinically significance since the differences of the total QOL score was less than 6.5 points (Jaeschke et al., 1989). The effect size was also small (3.1 percent).

By looking at the within-subject contrast, the APMRT improved the total QOL score by linear trend although the effect size was small (6.1 percent). The APMRT could achieve clinically significance if the therapy given was longer than six months with some improvement on the given therapy and the patients' compliance.

These results in this study support the findings of some previous studies that investigated the impact of different relaxation techniques on quality of life. Study by Cheung et al., (2003) among patients after stoma surgery found significant improvement in psychological health and social concern measured using QOL-disease specific and QOL-generic scales. Ghafari et al., (2009) found a significant improvement in quality of life improvement among multiple sclerosis patients and Dehdari et al., (2009) found the same result in all domains of quality of life after intervention in cardiac rehabilitation care. Ghafari et al., (2009) found significant difference between intervention and control groups by three fold among multiple sclerosis patients. However, a study by Cheung et al., (2003) needed to be interpreted cautiously since the analyses used t-test in multiple comparisons which may increase the chance of Type I error (Grimm, 1993).

Smith et al., (2007) found that relaxation therapy was more effective compared to yoga for improvement of quality of life. He suggested that relaxation therapy may be easier to incorporate and more practical in patients' daily life compared to yoga. Meanwhile, educational intervention by giving information on disease specifics and discussion about prostate cancer also improved the quality of life among prostate cancer patients (Lepore, Helgesan, Eton, & Schulz, 2003). The mechanism of improvement may be the same with the improvement in mental component summary. All the parasympathetic activities such as decreased blood pressure, heart rate, muscle tension, and rate of breathing, as well as feelings of being calm and in control may indirectly improve quality of life (Widmaier et al., 2006).

5.7.1.4 Self-reported health transition of the participants at baseline and at 6-months of the study

There were no significant differences in health transition in both groups at baseline and at 6-months. However the intervention group improved to a better condition by 4.8 percent from baseline to at 6-months.

5.7.2 Depression, Anxiety and Stress

Depression, anxiety and stress were assessed using Depression Anxiety Stress Scales version 21 (DASS-21) in English and Malay languages. The lower the score, the better is the psychological condition.

5.7.2.1 Outcome evaluation for Depression

There was no significant difference between intervention and comparison group (p=0.784) for the between-subject effect. APMRT did not seem to improve depression score among prostate cancer patients.

For within-subject effect for depression; in the intervention group, there was no significant decrease in depression scores from baseline to 4-months and from 4-months to 6-months. However, the depression score decreased throughout the study period. It can be concluded that the APMRT had slight improvement in depression score but not enough strong to made a significant different improvement. Among comparison group, there was also no significant decrease in depression scores from baseline to 4-months and from 4-months to 6-months.

The post-hoc multiple comparison and within-subject contrast for depression score was not explored since the between-subject effect analysis was not significant

Our study results was similar with the findings of the study by Lahmann et al., (2008a) which found that relaxation therapy was not effective in reducing depression among somatoform heart disorder patients with non-specific chest pain (p=0.973).

However, study by Leo´n-Pizarro et al., (2007) found that the relaxation technique was effective in reducing the level of depression among gynaecological and breast cancer patients who underwent brachytherapy (p=0.03), patients with night eating syndrome (Pawlow et al., 2003) and among irritable bowel syndrome patients (Boyce et al., 2003). The depression score was significantly decreased among heart failure patients (Yu et al., 2007) and among advanced cancer patients (Sloman,

2002). Yu et al., (2007) found a medium-size effect in reducing psychological distress (partial $\eta 2 = 0.7$) and Collins & Rice (1997) found significant improvement in depression level among myocardial infarction patients. In meta-analysis review, the relaxation training was effective in reducing depression score [effect size: 0.54 (95%CI: 0.30, 0.78)] in acute surgical cancer treatment (Luebbert, Dhame, & Hasenbring, 2001).

There were some reasons for the contradictory results. Having prostate cancer can cause worry and sadness which may put the patients at risk of experiencing depression. It also may lead to feeling isolated and therefore make it harder to recover from depression. The treatment for prostate cancer can cause changes in chemicals in the brain that can put men at greater risk of depression. For example; hormonal treatments are common in the treatment for prostate cancers and can cause mood changes such as depression. All of these could be the reasons why the impact of the therapy was not effective to reduce the level of depression among prostate cancer.

Systematic reviews found that the Alexander technique offered more benefits in managing depression (Kerr, 2000). Cognitive behavior therapy was effective in treating mild to moderate depression among females (Donaghy & Durward, 2000). Meanwhile, meta-analysis by Stetter & Kupper (2002) found autogenic training was beneficial in mild to medium depression. A combination of strengthening exercise and aerobics were also found to be useful for relieving depression (North, McCullagh, & VuTran, 1990).

5.7.2.2 Outcome Evaluation for Anxiety

The anxiety score was significantly improved in the intervention group ($p<0.001$) with a small effect size (15.7 percent). APMRT has an advantage to improve anxiety score among prostate cancer patients. The anxiety score was lower in intervention group compared to comparison group.

For within-subject effect; the anxiety score decreased significantly from baseline to 4-months and from 4-months to 6-months in the intervention group. For the comparison group, there was no significant decreased difference in the depression from baseline to 4-months and from 4-months to 6-months. It can be concluded that the APMRT had an advantage to improve the anxiety within the short period of time.

The post-hoc multiple comparison, it was found that the anxiety improved from baseline to 4-months ($p<0.001$) and not from 4-months to 6-months ($p<0.001$). The impact of APMRT on anxiety was only within short period of time. The effect sizes were also small (10.3 percent and 13.3 percent).

By looking the within-subject contrast, the APMRT improved the anxiety score by linear trend although the effect size was small (25.6 percent). The clinically significance could be achieved if the APMRT was given longer than six months with some improvement done on the therapy given and the patients' compliance.

Our results supported the findings of some previous studies that investigated the impact of different relaxation techniques on anxiety. The improvement was found among pregnant women in reducing state-anxiety and trait-anxiety (Bastani et al., 2005), undergraduate physical therapy students on reducing cognitive and somatic

anxieties (Gill et al., 2004), and among acute schizophrenia (Chen et al., 2009). Relaxation therapy also improved the anxiety among colorectal cancer patients after surgery (Cheung et al., 2003).

There were other studies that showed significant difference in many different relaxation techniques in reducing anxiety level such as in dental fear patients (Lahmann et al., 2008b), night eating syndrome patients (Pawlow et al., 2003), post coronary bypass graft surgery patients who underwent rehabilitation care (Dehdari et al., 2009) and among irritable bowel disease (Boyce et al., 2003). Study by Mackereth et al., (2009) found that combination between reflexology and relaxation therapy significantly reduced anxiety among multiple sclerosis patients. The combination between relaxation techniques and guided imagery were found effective in reducing the level of anxiety in dental fear patients (Berggren et al., 2000) and among breast cancer patients (Leo´n-Pizarro et al., 2007).

A systematic review from six databases (Google Scholar, MEDLINE, PsycINFO, PubMed and Web of Science) by Matthew et al., (2010) found that exercise training reduced anxiety symptoms among sedentary patients by a mean effect of 0.29. In another systematic review among acute surgical cancer treatment patients, the relaxation training was effective in reducing anxiety score (effect size: 0.45) (Luebbert et al., 2001). The abbreviated progressive muscle relaxation was effective in the treatment of generalized anxiety (Charles & Rick, 1993). Manzoni et al.,(2008) also found the relaxation training showed a medium to large effect size for anxiety disorder.

The effectiveness of the relaxation therapy on reducing anxiety level could be due to the stimulation of parasympathetic activity that cause a decrease in blood pressure, heart rate, muscle tension, and rate of breathing, as well as feelings of being calm and in control and this can indirectly reduce the anxiety (Payne, 2000). Sharpley and Christie (2007b) also found that the anxiety level decreased due to reduction in psychomotor agitation, weakness and pessimism.

Although many relaxation studies had advantages on anxiety, Yu et al., (2007) did not find any significant reduction among heart failure patients. Collins & Rice (1997) suggested that more instruction session on relaxation therapy are required in order to get more positive outcome when they found no significant improvement in anxiety level among myocardial infarction patients. Study by Rashid & Parish (1998) found that the trait-anxiety was not reduced among high school students due to resistance to change in personality make-up.

Non-pharmacological treatments for anxiety disorder are increasingly practised. The relaxation techniques represent the most used approach in anxiety management as stand-alone or combined with other therapies that are highly efficient and produce long-term benefits (Bernstein & Borkovec, 1973). Breathing retraining can lower the respiratory rate and anxiety level among patients with anxiety disorder (Han, Stegen, De Valek, Clement, & Van de Woestijne, 1996). Reducing anxiety is one potential motivation for screening, because individuals may hope for reassurance from a normal test result among prostate cancer patients (Dale, Bilir, Han, & Meltzer, 2005).

5.7.2.3 Outcome Evaluation for Stress

The stress score changes were significantly improved between intervention and comparison group ($p<0.001$) with small effect size (11.6 percent). It indicated that APMRT had an advantage in reducing stress among prostate cancer. The stress score was lower in intervention group compared to comparison group.

For within-subject effect; the anxiety score decreased significantly from baseline to 4-months and from 4-months to 6-months in the intervention group. For the comparison group, there was no significant decreased difference in the depression from baseline to 4-months and from 4-months to 6-months. It can be concluded that the APMRT had an advantage to improve the anxiety within the short period of time.

The post-hoc multiple comparison, it was found that the stress improved from baseline to 4-months ($p<0.001$) and not from 4-months to 6-months ($p<0.001$). It supported the result on the within-subject effect that showing the impact of APMRT on stress was only within short period of time. The effect sizes were also small (7.7 percent and 9.1 percent).

For the within-subject contrast, the APMRT improved the stress score by linear trend although the effect size was small (11.6 percent). The APMRT could achieve the clinically significant if the therapy was given longer than six months with some improvement on the therapy given and the patients' compliance.

Our results supported the findings of some previous studies that investigated the impact of different relaxation techniques on stress improvement among night eating syndrome patients (Pawlow et al., 2003), undergraduate students (Pawlow & Jones,

2002), pregnant women (Bastani et al., 2005) and healthy young adults (Emery et al., 2008). Pawlow & Jones (2002) found consistent changes in reducing stress and significantly lower salivary cortisol level during relaxation therapy.

Yu et al., (2007) found a medium-size effect (partial η^2= 0.7) in alleviating psychologic distress in patients with chronic illness. In one meta-analysis, an abbreviated progressive muscle relaxation (APRT) is an effective treatment for the reduction of stress with moderate effect size (Charles & Rick, 1993). Kerr's systematic review (2000) also found relaxation therapy was to be effective in reducing physiological and psychological stress.

The reason for the improvement in stress is almost the same with the improvement for anxiety. The effect of relaxation for the stimulation of parasympathetic activity causes a decrease in blood pressure, heart rate, muscle tension, and rate of breathing, as well as feelings of being calm and in control and this indirectly reduce stress (Payne, 2000). Conducting prospective study was found to demonstrate better improvement in the stress level compared to cross sectional study (Charles & Rick, 1993).

5.7.2.4 Categories of Depression, Anxiety and Stress of the Participants at Baseline and at 6-month of the Study

5.7.2.4.1 Depression

In the six months of our study, there was no significant difference in the proportion of depression at baseline and 6-months in intervention and comparison groups. The proportion of depression decreased by 1.5 percent in the intervention group but

increased by 1.6 percent in the comparison group. However, study by Sharpley et al., (2007) found that the depression level decreased clinically from 24 percent to 12.5 percent after 24 months of diagnosis. This contradicting could be due to shorter period of time in our study.

5.7.2.4.2 Anxiety

The proportion of anxiety was decreased from 31.4 percent to 21.4 percent in the intervention group but increased from 29.4 percent to 32.4 percent in comparison group. Similar results were shown by Cheung et al., (2003) where they also found a decrease in anxiety score after applying the progressive muscle relaxation among post stoma surgery. However, the proportion in our study was less than Cheung et al., (2003) by 15 percent. It could be due to shorter time period in this study. Cheung et al., (2003) concluded that PMR can be a coping strategy to reduce anxiety associated with the consequences of cancer treatment.

Observational study by Sharpley & Christie (2007b) found the anxiety level decreased clinically from 20 percent to 12 percent after 24 months of diagnosis without any intervention. They described the changes in anxiety over time in was largely somatic. Our comparison group did not showed any different over time chould be due to the short period of time. Our comparison group did not showed any significant difference over time probably due to the short period of time and anxiety in prostate cancer was actually a part of the ongoing disease process (Wilkinson et al., 2008).

5.7.2.4.3 Stress

Throughout the study period, the proportion of stress in the intervention group decreased by 2.9 percent. Meanwhile, among comparison group the proportion increased by 1.4 percent. The finding was not significant and could be due to chance.

5.7.3 The correlation between frequency of practicing Applied Progressive Muscle relaxation Training (APMRT) and the scores of depression, anxiety and stress and the scores of health related quality of life (HRQOL)

The correlation between frequency of practicing APMRT and the scores of depression, anxiety and stress and HRQOL could not be carried out due too many missing values in the frequency of practicing APMRT. Study by Yu et el., (2007) found that the frequent home practice was significantly related to the improvement in psychological outcome (anxiety score: r=-0.37, p=0.004; depression score: r=-0.74, p<0.001). Study by Cheung et al., (2003) also showed a significant correlation between frequency of practicing relaxation therapy and the scores for anxiety and quality of life. Those who practiced relaxation therapy more frequently reported higher quality of life and lower state of anxiety. In the meta-analysis by Charles & Rick (1993) it was found that treatment duration and number of relaxation sessions positively influenced in reducing level of stress.

The effectiveness of relaxation therapy decreased after termination of the relaxation therapy, therefore it need to be practiced continuously to show the impact of the therapy (Yoo et al., 2005). Cheung et al., (2003) also concluded that higher frequency of practice did not contribute for a better adjustment after therapy was stopped.

5.8 Strengths and limitations of the study

5.8.1 Strength of this therapy

As a whole, this relaxation therapy achieved an improvement in anxiety and stress; and also an improvement in the mental component summary (MCS) and total quality of life (QOL) for health related quality of life (HRQOL). Although there were some improvements, clinically APMRT only produced low effect sizes. There were no significant improvement in the depression and physical component summary. However, this study possessed several strengths

5.8.1.1 Homogeneity of the participants

A quasi-experimental study has been conducted in this study. Comparability of the participants' characteristics in both groups was very important. The analysis for all the variables for comparability was found not statistically significant. It can be concluded that the populations in both groups were similar.

5.8.1.2 Location of the study

As mentioned in the methodology, two medical centres were selected in the study. Both of the centres were far from each other. The coverage areas for both medical centres were also different. This can reduce the effect of contamination since patients from UMMC did not know the patients in UKMMC who were involved in the study and vice versa.

5.8.1.3 Data Analysis

The mixed design analysis of variance (ANOVA) was used in the analysis. This analysis is the most suitable in any trial since it reduce the possibility of having the chance of Type I error compared to if the analysis used difference of mean difference. Repeated measure ANOVA can make the analysis more efficient and helps to keep low variability and high validity.

5.8.1.4 Script of relaxation therapy and compact disc instruction

Adherence to a script in relaxation therapy sessions and the use of a compact disc instruction for at-home practice promoted consistency in implementation of APMRT. This six month period of follow up enabled us to better understand behavioural change occurring in free living participants. When the patients forget the instruction, they can refer back to the script for revision.

5.8.1.5 Data collection

The data collection was done only by principal investigator alone. It can reduce inter-rater bias assessment.

5.8.1.6 Follow up

There was low percentage of loss of follow up in this study. Keeping in contact with the patients was the strategy to achieve high response. The results of the study were better for analysis and interpretation.

5.8.1.7 Type of analysis

Intention to treat (ITT) analysis was used in this study. The results of tan experiment was based on the initial assignment and not on the treatment eventually received. ITT was intended to avoid various misleading artifacts that can arise in intervention research such as non-random attrition of participants. ITT has also simpler that other form of study design and nalysis because it does not require observation of comlinace status for unit assigned to different treatment or incorporation of compliance into the analysis.

5.8.2 Limitations of the study

5.8.2.1 Study design

As mentioned in methodology, a quasi-experimental design conducted in this study was the best option. A quasi-experimental design was conducted due to limitation of resources and shortage of time on conducting the study. As this was an open label study, the problem of contamination cannot be avoided if randomization study was conducted in one centre. At baseline, the socio-demographic, past medical and surgical history and current urinary problems and current cancer status were comparable between two groups.

The selection of patients was well defined with the inclusion and exclusion criteria, to minimize misclassification bias. Both groups of the patients were recruited from the surgical clinics of UMMC and UKMMC. UMMC and UKMMC are the tertiary medical centres under the Ministry of Higher Education, Malaysia (Ministry of Higher Education Malaysia, 2011). The generalizability of our finding is limited to

prostate cancer patients followed up at tertiary hospitals. However, utilizing a quasi-experimental minimized the threats to external validity and the findings still can be allowed for some generalization to be made on the target population.

Blinding is a basic tool to prevent conscious and unconscious bias in research. In this study, neither the investigator nor the patients were blinded to the Intervention. The perceptions about the advantages of one treatment over another can influence assessments of outcomes. Therefore self-reported HRQOL and DASS may be influenced since the respondents knew in which group they were.

5.8.2.2 Response, non-response and selection biases

The sampling method conducted in this study had a tendency to non-sampling error like selection bias, response bias and non-response bias. Voluntary bias is the major issue. Patients who were willing to participate in the study may be different from patients who declined to participate. However, Table 4.12 showed no significant differences between respondents and non-respondents.

5.8.2.3 Information bias

Information bias is a dominant feature in these studies that interferes with the validity of the outcome. The data on the possible exposure collected retrospectively and the patients had to recall the exposure factor. The information bias may be caused by poor memory associated with old age of patients. Therefore, inaccuracies may occur in reporting the information. To reduce the information bias, face to face interview was conducted where the investigator could clarify the information given

by the patients. Furthermore, information such as past medical and surgical illnesses was verified with the patient's medical record. The interview was conducted by the principal investigator to reduce inter-observer bias.

5.8.2.4 Missing data from the secondary data

There were missing data from the medical record such as PSA level at time of diagnosis, past medical and surgical illnesses. However the missing data were less than 10.0 percent, so the analysis was based on the complete data.

5.8.2.5 Poor compliance of the patients

The frequency of practicing APMRT at home was unknown since less than ten percent returned the log books. Moreover, the logbooks were incomplete and could not be analysed. Those returned logbooks were self-reported. It was not known whether the respondents' practised the entire or only some parts of APMRT at home. Compliance problems have been identified as an important factor in compromising the effectiveness of relaxation training.

5.9 Study Implications

This study is aimed to determine the impact of the applied progressive muscle relaxation training on the levels of depression, anxiety, stress and general health related quality of life (HRQOL) among prostate cancer patients.

The descriptive findings of depression, anxiety, stress and quality of life provide the information on: (i) how prostate cancer patients perceived or evaluated their situation as being depressed or not depressed, anxious or not anxious and stressful and not stressful and (ii) the severity of depression, anxiety and stress experienced by prostate cancer patients. This information reinforced the need for health care providers to recognize symptoms related in prostate cancer patients for example, health care provider may need to provide effective intervention for urinary symptoms and sexual dysfunction among prostate cancer patients.

As APMRT has produced encouraging results in this study, such as improving the mental component score, it is suggested that APMRT should be offered to prostate cancer patients as routine care. It can be initiated as soon as the patients are diagnosed with prostate cancer. Offering the intervention may also assist in decreasing anxiety and stress due to the cancer. The approach could be transformed into counseling patients as "body-mind whole person" from a more holistic viewpoint that make integrative medicine the next challenge for tomorrow's clinical practice with the aim of a real heal by respecting patients in all dimension and creating a positive emotions (Janssen, 2008).

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusions

6.1.1 Baseline psychological problems and health related quality of life

At baseline, the percentages of depression and stress among prostate cancer patients were relatively low; while the percentage of anxiety was moderately high. However, there were no patients classified with very severe depression, anxiety and stress. The prostate cancer patients also reported to have an average quality of life. The MCS score was higher compared to the PCS score.

6.1.2 The impact of Applied Progressive Muscle Relaxation Training on psychological problems and health related quality of life

The mental component summary (MCS) and total quality of life (QOL) increased significantly and the level of anxiety and stress decreased significantly. The levels of MCS, anxiety and stress improved from baseline to 4-months and from 4-months to 6-months, while for total QOL it only improved from baseline to 4-months, but not from 4-months to 6-months. Even though there were improvements statistically, the effect sizes did not achieve clinical significance. There was no significant improvement in physical component summary (PCS) and depression.

When the analysis was carried out by categories for psychological problem, the APMRT did not showed any improvement for anxiety and stress after 6 months. Although the results were clinically unsignificant, APMRT showed promising effect on the psychological problems and quality of life among prostate cancer patients. The APMRT should be maintained to ensure that all improvements in general health-

related quality of life as well as psychological distress among prostate cancer patients can be sustained in the future.

6.2 Recommendations

6.2.1 Result-based recommendations

Although our result show small effect size suggesting lack of clinical significance, it can be concluded that, APMRT had benefit in prostate cancer care and there is a need to integrate APMRT into the management for prostate cancer. “Small” effect size may be worthwhile and should not be automatically ignored. The issues of cost-benefit often come into play.

Since the study found a small impact in the therapy, more occupational therapist need to be trained. However, the issues of cost-benefit often come into play. The cost of producing the staff need to be considered too that can be more benefit to the patients as well. For example, if the relaxation therapy is relatively inexpensive to provide (in terms of financial, provider and time investment) and results in small effect sizes, this may still be far more favourable compared to another program with far greater costs yet only slightly larger effects. There is no formal credential or license required for practising or teaching most relaxation therapy. However, the techniques may be used to teach by a licensed professional including physician, recreational therapist and psychologist.

The effectiveness of the therapy need to be considered. The planning on how to make the therapy more effective need to be discussed on such as how to make

patients come to the hospital for the therapy and to ensure good compliance of patient towards to therapy.

The success in the integration of APMRT into clinical practice needs full support and planning from the administrative and health personnel. Furthermore, prostate cancer patients should maintain the practice of APMRT in their daily life since it can be done at home during their free time by following the instruction of the CD.

Recognising and respecting the three elements in a person which are physical, emotional and intellectual could improve the efficacy of treatment and stimulate the inner healing potential of the patients. Living after cancer needs some programmes such as relaxation therapies which can help cancer survivors to improve their long term prospect and quality of life. General relaxation may reduce anxiety and depression, improve mood, boost self-esteem and reduce fatigue that can be relaxing both physically and mentally.

Interdisciplinary treatment is very important for prostate cancer patients. This is a form of prevention and it must provide the basic and general information on chronic disease such as prostate cancer. Positive attitude towards the elderly should be promoted; education and healthy lifestyles should be directed to the prostate cancer patients. Individual counseling during clinic visits can be helpful to reinforce and improve existing knowledge. Close teamwork between the surgeons, oncologist, radiologist, pathologist and other relevant disciplines improves the quality of cancer treatment for individual patients and encourages developing management policies. Clinician-patients communication is a fundamental of cancer care that significantly affect the therapeutic relationship, the well-being of patients and families, treatment

decision-making and compliance, and the capacity of patients and families to plan for alternative treatment of the disease and treatment course. Continuity of care among prostate cancer after discharge is still needed as their basic cancer care.

6.2.2 Other related recommendations: Lesson learnt from this research

The investigator hopes that the result of this study may be used as a stepping-stone for the health care provider to look into the importance of APMRT as an additional therapy to improve some psychological and health related quality of life. Information about APMRT should be made available by using pamphlets, posters, television advertisements to assist prostate cancer patients to impove their quality of life.

To promote the APMRT, the training of healthcare providers is essential. This training could be one of the important components in the syllabus for occupational therapists and clinical psychologist students. For the existing healthcare professionals involved in direct patients care, the APMRT can be promoted for other cancer patients after giving the patients a training session to enhance their knowledge and skills in APMRT.

Majority of the prostate cancer patients are elderly. Therefore, the government and non-governmental organization (NGO) such as Gerontology Association of Malaysia (GeM) and The National Council of Senior Citizen Organization of Malaysia (NACSROM) need to explore the varying needs of the elderly, their challenges and future approaches. So, APMRT also can be promoted to NGOs for promotion and preventive health care among elderly. Establishing APMRT in geriatric services at

state and national levels can increase their quality of life through community-based approach.

6.2.3 Recommendations for future research

There are some modifications that can be recommended for further research:

First, future studies should be carried out over a longer period. Some of the significant findings like mental component summary, total quality of life, anxiety and stress showed a significant linear trend but small effect sizes. The bigger effect sizes may be produced when the study period is conducted over a longer period.

Second, the quasi-experimental trial design was used in this study. It is better to carry out a randomized control trial (RCT) to reduce the biases associated with quasi-experimental design. A Cluster RCT can be conducted when there have many resources in order to avoid the problem of contamination during randomization.

Third, the cut-off percentiles for depression, anxiety and stress by using DASS-21 were based on the Australian population**.** Since this study was done on Malaysian population, it is better to have Malaysian population own cut-off percentiles for the classification of the depression, anxiety and stress. Involvement of the psychiatrist is needed in the study for the agreement whether the patients had significant depression, anxiety and stress.

Fourth, the population of Malaysia consists of three major ethnic groups such as Malay, Chinese and India. In this study, only English and Malay languages version of DASS-21 and SF-36 were used for the assessment. So, a validated translation of

other languages like Chinese and Tamil should be developed in future to suit the patients' needs.

Fifth, use of multiple instruments enabled researchers to generate more reliable, comparable, valid and sensitive measurements. It has been found that using single quality of life instrument as an outcome indicator may not be sensitive to detect quality of life changes. For example, the assessment for the health related quality of life (HRQOL); SF-36 questionnaire and the UCLA-Prostate Cancer Index (PCI) questionnaire are given at the same time. Multiple instruments approach also allows for a broader conceptualization of quality of life. Therefore, the consistency of the HRQOL can be assessed by using multiple instruments.

Assessment for depression, anxiety and stress can be done by using the DASS questionnaire and Hospital Anxiety Depression Scale (HADS) for anxiety and depression, Spielberger State-Trait Anxiety Inventory (STAI) for anxiety, Beck Depression Inventory (BDI) for depression and other self-reported questionnaire that can assess these psychological problems. More comparisons is needed for multiple modalities, using validated instruments will help prostate cancer patients to make their own decision in treatment.

Sixth, further study on the ideal frequency and time interval of practicing APMRT are needed. As most studies have been carried out in different settings, different frequencies and time intervals, so recommendations can be made over frequency or intervals of APMRT practice.

7.0 References

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APPENDIX A: Abdominal Breathing Instruction

English Version

UNIVERSITY OF MALAYA
KUALA LUMPUR
UM MEDICAL CENTRE

BREATHING EXERCISE

1. Concentrate on your breathing
2. When you inhale feel of cool air passing through your nose (1 minute)
3. Concentrate on your exhalation (1 minute)
4. Now make your exhalation a little longer than inhalation (1 minute)
5. Concentrate on your exhalation
6. Your exhalation is long and easy (1 minute)
7. Try to imagine that your breathing is like a wave
8. Your breathing should go smoothly and without effort (2 minutes)

Malay Version

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UM MEDICAL CENTRE

LATIHAN PERNAFASAN

1. Tumpukan pada pernafasan anda
2. Bila anda menarik nafas, rasa udara yang sejuk melalui hidung (1 minit)
3. Tumpukan pada hembusan nafas anda (1 minit)
4. Sekarang lakukan hembusan nafas anda sedikit lama daripada menarik nafas (1 minit)
5. Tumpukan pada hembusan nafas anda
6. Hembusan nafas anda panjang dan selesa
7. Cuba bayangkan pernafasan anda seperti alunan ombak
8. Pernafasan anda seharusnya dilakukan secara lembut tanpa paksaan (2 minit)

APPENDIX B: Applied Progressive Muscle Relaxation Training Instruction

English Version

UNIVERSITY OF MALAYA
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UM MEDICAL CENTRE

PROGRESSIVE MUSCLE RELAXATION (1)

Sit comfortably and close your eyes
Rest your neck in a comfortable position
Try to think of nothing
Listen to my voice and follow my instruction

Your forehead muscle are relaxed
Your lower jaw is relaxed
Your tongue is relaxed
Your face feels soft and warm and is like a mask of calmness
Your neck muscle are relaxed
You feel warmth in the back part of your neck
You feel warmth in your upper arms

You feel warmth in your hands
You feel pulsation in your fingertips
You feel inner silence
Your breathing is even and easy
Your heart is relaxed
You feel warmth in the plexus
Your belly is relaxed
Your lower back is relaxed
Your thighs are relaxed
Your legs are relaxed
Your feet are warm
You feel the tips of your toes
All parts of your body are warm and relaxed
Your breathing is even and easy
You are calm

Slowly put your palm on your close eyes
Under the palm blink and open your eyes smile

PROGRESSIVE MUSLCE RELAXATION (2)

Be comfortable
Find a relaxing position for your body
Please pay attention to my instructions
Close eyes please and listen to my voice

Concentrate on your right toe
Feel it
Just feel that you have right toe
Your attention is on the right toe
Feel the right foot
Focus on it
Feel the right knee
Feel the right hip
Feel the right buttock
Feel know the whole right leg lies heavily on the floor

(*You can already feel, if you compare this leg to the another, that your right leg is relax, is heavier, probably warmer because you have concentrate your attention on it*)

Now feel the left toe
Feel the left foot
Feel the left knee
Feel the left hip
Feel the left buttock
Feel now the whole left leg lies heavily on the floor
Feel your lower back. Focus on it

And now feel your right thumb
Feel the right hand
Feel the right elbow
Feel the right shoulder
Feel the right shoulder blade
Your right arm is relaxed and you don't want to move it. Let it rest.

And now feel your left thumb
Feel the left hand
Feel the left elbow
Feel the left shoulder
Feel left shoulder blade
Your left arm is relaxed and you don't want to move it. Let it rest.

Feel your upper back
Feel the back part of your neck
Feel your nape

Feel the front part of your neck
Feel your forehead
Feel your eyebrows sagging down
Feel the right check
Feel the left check

Your cheeks become heavier and start to drop under their own weight
Feel your lips. They are lazy and soft
Feel your tongue, it is relaxed in your mouth, completely relaxed
Feel your chin. It grows heavy as if something is pulling it downwards
Feel your chin and allow your jaw to drop slightly
Feel the front part of your neck
Imagine that the neck is dropping
Now focus on your breathing
Simply observe it
Feel the rise and fall of your chest and stomach …
… as your breath flows slowly in and slowly out.

Slowly put your palm on your close eyes
Under the palm blink and open your eyes smile

Malay Version

UNIVERSITY OF MALAYA
KUALA LUMPUR
UM MEDICAL CENTRE

PROGRESSIVE MUSCLE RELAXATION (1)

Duduk dengan selesa dan pejamkan mata anda
Rehatkan tengkuk anda pada posisi yang paling selesa
Cuba untuk tidak memikirkan sesuatu
Dengar suara saya dan ikut arahan saya

Rehatkan otot dahi anda
Rehatkan rahang bawah anda
Rehatkan lidah anda
Muka anda akan berasa lembut dan selesa menunjukkan ketenangan
Rehatkan otot tengkuk anda
Anda akan berasa selesa di bahagian belakang tengkuk anda
Anda akan berasa selesa di lengan atas anda

Rasakan keselesaan di tangan anda
Rasakan denyutan nadi di hujung jari anda
Anda akan berasa ketenangan di dalam diri anda
Pernafasan anda mudah dan menjadi lebih senang
Rehatkan jantung anda
Anda akan merasakan ketenangan di bahagian belakang anda
Rehatkan perut anda
Rehatkan bahagian belakang pinggang anda
Rehatkan betis anda
Rehatkan kaki anda
Rehatkan jari kaki anda
Anda rasakan hujung jari kaki anda
Semua anggota badan anda selesa dan tenang
Pernafasan anda mudah dan menjadi lebih senang
Anda berasa tenang…..

Perlahan-lahan letakkan telapak tangan anda diatas mata anda yang tertutup
Di bawah telapak tangan anda, buka mata anda secara perlahan lahan dan senyum

PROPRESSIVE MUSCLE RELAXATION (2)

Duduk dengan selesa dan pejamkan mata anda
Rehatkan tengkuk anda pada posisi yang paling selesa
Cuba untuk tidak memikirkan sesuatu
Dengar suara saya dan ikut arahan saya

Tumpukan perhatian kepada ibu jari kaki anda
Rasakannya
Cuba rasakan anda mempunyai ibu jari kaki kanan
Tumpukan perhatian jari kaki kanan anda
Rasa kaki kanan
Tumpukan padanya
Rasa lutut kanan
Rasa pinggul kanan
Rasa ponggong kanan
Rasa kesemua kaki kanan berada di atas lantai

Sekarang rasa ibu jari kaki kiri
Rasa kaki kiri
Rasa lutut kiri
Rasa pinggul kiri
Rasa ponggong kanan
Sekarang rasa seluruh kaki kiri berada di atas lantai
Rasakan belakang bawah tubuh anda dan tumpukan kepadanya

Sekarang rasa ibu jari kanan anda
Rasa tangan kanan anda
Rasa siku kanan
Rasa bahu kanan
Rasa hujung bahu kanan
Lengan kanan anda tenang dan jangan gerakkan lengan anda itu. Biarkan ia dalam keadaan rehat.

Sekarang rasa ibu jari kiri anda
Rasa tangan kiri anda
Rasa siku kiri
Rasa bahu kiri anda
Rasa di hujung bahu anda
Lengan kiri anda tenang dan jangan gerakkan lengan anda itu. Biarkan ia dalam keadaan rehat.

Rasa badan anda di bahagian belakang
Rasa leher anda di bahagian belakang

Rasa tengkuk anda
Rasa bahagian depan leher anda
Rasa dahi anda
Rasa kening anda
Rasa pipi kanan anda
Rasa pipi kiri anda

Pipi anda akan berasa berat dan mula jatuh pada beratnya sendiri
Rasa kelembutan bibir anda
Rasa lidah anda, ianya tenang dan rehat di dalam mulut anda sepenuhnya.
Rasakan dagu anda. Ia nya berasa berat jika ada sesuatu yang menariknya ke bawah
Rasa dagu anda dan benarkan rahang anda sedikit jatuh
Rasa di depan leher anda
Bayangkan ianya jatuh
Sekarang tumpukan pada pernafasan anda
Dengan mudah perhatikannya
Rasa turun dan naik dada dan perut anda
... seperti mana pernafasan anda ketika menghembus nafas

Perlahan-lahan letakkan telapak tangan anda diatas mata anda yang tertutup
Di bawah telapak tangan anda, buka mata anda dan senyum

APPENDIX C: End of Relaxation Session Instruction

English Version

UNIVERSITY OF MALAYA
KUALA LUMPUR
UM MEDICAL CENTRE

END OF RELAXATION SESSION

Now you feel relaxed
And you can return to this peaceful state whenever you want to
Take a few moments now to get to know this feeling ….. all over your body …
And memorize it as carefully as you can
So that you can recall it letter whenever there is a need to do so.
Now slowly return to this place, listening to my voice, keeping your eyes still closed
Slowly stretch your arms upward
Feel your arm stretching, feel your back stretching.
Stretch yourself slowly but as much as you like
Enjoy the feel of your body, your muscle, and all the part of your body that are awakening now.

You feel new energy now
Slowly put your palm on your close eyes
Under the palm blink and open your eyes smile

Malay Version

UNIVERSITY OF MALAYA
KUALA LUMPUR
UM MEDICAL CENTRE

SESI AKHIR ISTIRAHAT

Sekarang anda rasa tenang
Dan anda akan kembali dalam keadaan aman bila bila sahaja yang anda mahukan
Ambil beberapa minit untuk mendapatkan perasaan …. di seluruh tubuh anda …
Dan cuba mengingatinya sedaya upaya anda secara cermat
Dan dengan itu anda akan cuba mengingati kembali apabila anda perlu untuk melakukannya lagi
Sekarang secara perlahan lahan, dengar suara saya dengan mata yang masih tertutup
Perlahan lahan renggangkan lengan anda ke atas
Rasa renggangan lengan dan belakang badan anda
Renggangkan diri anda perlahan lahan dengan sebanyak mana yang anda mahukan
Nikmati apa yang anda rasakan di tubuh, otot dan semua bahagian di tubuh anda yang sekarang berasa bertenaga
Anda akan rasa bertenaga sekarang
Perlahan-lahan letakkan telapak tangan anda diatas mata anda yang tertutup
Di bawah telapak tangan anda, buka mata anda dan senyum

APPENDIX D: Relaxation worksheet

Name: _____

NOIC : _____

Relaxation is a skill that developes with practice. While you are learning how to use progressive muscle relaxation (PMR), it is important that you practice daily. Complete the following Monthly Relaxation Worksheets and bring it to the next meeting. Next to each category, indicate the appropriate information about your daily practice.

For the degree of relaxation: "0 = very relaxed ……. , 10= very tense"

Date							
Day							
Time started							
Time stopped							
Degree of relaxation of start							
Degree of relaxation at the end							

APPENDIX E: Background Questionnaire

Address:
Dr. Mohamad Rodi bin Isa
MBBS, DAP&E, MPH
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Faculty of Medicine
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THE IMPACT OF THE APPLIED PROGESSIVE DEEP MUSCLE RELAXATION TRAINING TO THE LEVEL OF DEPRESSION, ANXIETY, STRESS AND QUALITY OF LIFE AMONG PROSTATE CANCER PATIENTS

These questions are about the prostate cancer patient's background. It has been developed about prostate cancer patients in University Malaya Medical Centre. The information will be used to develop better knowledge about the characteristics of prostate cancer.

All responses are completely CONFIDENTIAL to the researchers and will be analyzed as a total group. Therefore, CONFIDENTIALITY is assured and no responses are separately identifiable.

Thank you very much for your help

Yours sincerely,

…….
Dr. Mohamad Rodi bin Isa
MBBS, DAP&E, MPH
Principle Investigator

ID no:

Questionnaire:

Name :

_____

NOIC : _____ - _____ - _____ NOIC (Old) : _____

Date of Birth : _____ - _____ - _____

Hospital Registration number : _____

Home address : _____

_____

Home number : _____ Handphone: _____

Date of interview : _____ - _____ - _____

Part A: Socio-demographic section	
1. Age at interview : _____ years old 2. Ethnicity: ☐ Malay ☐ Chinese ☐ Indian ☐ Others : Specify : _____ 3. Religious: ☐ Muslim ☐ Buddist ☐ Hindu ☐ Christian ☐ Others Specify: _____ 4. Marital status: ☐ Married ☐ Not Married ☐ Widow/Separated/Divorced 5. How many children (+ if has adopt child) : _ 6. Living condition: ☐ Alone ☐ with partner ☐ with family ☐ with friend 7. Educational status: ☐ Higher/College/University ☐ Secondary ☐ Primary ☐ Not going to school	8. Still working: ☐ Yes ☐ No 8a. If Yes, What is the occupation : _____ 8b. If No, what is the last occupation: _____ 9. Family income : RM _____ per month 10. Payment of the treatment: ☐ Own pockets ☐ Retirement card ☐ Insurance ☐ Guarantee letter ☐ Other , specify : _____ 11. Smoking: ☐ Non Smoker ☐ Former smoker ☐ Current Smoker : _____ sticks/day 11a. If Former and current smoker, at what age start smoking : _____ years old 12. Drinking: ☐ Non Drinkers ☐ Former Drinkers ☐ Current Drinkers 13. Drug history: ☐ Non drug addict ☐ Former drug addict ☐ Current drug addict

Part B : Past medical and Surgical Illnesses

14. Past medical illness

☐ Yes
☐ No

.14a. If Yes,

i.	Asthma	: ☐ Yes	☐ No
ii.	Tuberculosis	: ☐ Yes	☐ No
iii.	Hypertension	: ☐ Yes	☐ No
iv.	Heart disease	: ☐ Yes	☐ No
v.	Allergy / Eczema	: ☐ Yes	☐ No
vi.	Diabetes Mellitus	: ☐ Yes	☐ No
vii.	Stroke	: ☐ Yes	☐ No
viii.	Hypercholesterolemia	: ☐ Yes	☐ No
ix	Gout	: ☐ Yes	☐ No
x.	Others : _____		
	: _____		
	: _____		

15. Past Surgical illness:

☐ Yes
☐ No

15a. If Yes, what is (are) the surgical illness:

i.	
ii.	
iii	
iv.	

16. Family history of prostate cancer:

☐ Yes
☐ No

I16a. f yes, who?

☐ Father
☐ Grandfather
☐ Sibling
☐ Uncle

17. Family history of other cancer

☐ Yes
☐ No

17a. If yes, who? and what type of cancer

i.	
ii.	
iii.	
iv.	

18. Current medication

☐ Yes
☐ No

18a. If Yes, what is(are) the medication(s) (specify):

i.	
ii.	
iii.	
iv.	

Part C: Presenting symptoms

Presenting complaint(s)

i.	Frequency (Have to urinate again less than 2 hours after you finished urinating)	: ☐ Yes	☐ No
ii.	Urgency (Find it difficult to postpone urination) ……	: ☐ Yes	☐ No
iii.	Nocturia (typically get up to urinate from the time you went to bed until the time you got up in the morning) ……..…	: ☐ Yes	☐ No
iv.	Satisfy with the stream ……	: ☐ Yes	☐ No
v.	Intermittency (Have you stopped and started again several times when you are urinating) ……	: ☐ Yes	☐ No
vi.	Straining (Have to push or strain to begin urination) ……	: ☐ Yes	☐ No
vii.	Dysuria (Pain during urination) ……	: ☐ Yes	☐ No
viii	Hematuria (Urine mix with Blood) ……	: ☐ Yes	☐ No
ix.	Incomplete Emptying (Have sensation of not emptying your bladder completely after you finish urinating) ……	: ☐ Yes	☐ No

Others: _____
: _____

Part D: Cancer Status

1. PSA level before the diagnosis : _____ ng/mL
   (date taken : _____ / _____ / _____)

2. Histology result (TRUS Biopsy) : (Date of biopsy: _____ / _____ / _____)
_____
_____
_____

3. Gleason Score : _____ + _____ = _____

4. CT scan report : (Date of CT scan : _____ / _____ / _____)
_____
_____
_____

5. Bone scan report: (Date of CT scan : _____ / _____ / _____)
_____
_____
_____

6. Type of treatment :

	Prostatectomy (Orchidectomy)
	Radiotherapy
	Prostatectomy and Radiotherapy
	Others (Specify : _____

6a. If Radiotherapy: Report nuclear medicine. (Date of CT scan : _____ / _____ / _____)
Radionuclide whole bone scintigraphy:
_____
_____
_____

7. The latest PSA level : _____ ng/ml
(date taken : _____ / _____ / _____)

APPENDIX F: Depression, Anxiety, Stress Scale (DASS-21)

English Versions

NAME : _____ DATE : _____

Depression, Anxiety and Stress Scale (DASS-BI)-21

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no rights or wrong answers. Do not spend too much time on any statement.

The rating scale is as follow:

0 **Did not apply to me at all.**
1 Applied to me **to some degree or some of the time.**
2 Applied to me **to a considerable degree or a good part of time.**
3 Applied to me **very much or most of the time.**

No.	Questions	Circle one number in each line Scale			
1(S1)	I found that life wasn't worthwhile ……..……	**0**	**1**	**2**	**3**
2(A1)	I was a ware of dryness of my mouth	**0**	**1**	**2**	**3**
3(D1)	I couldn't seem to experience any positive feeling at all. ……	**0**	**1**	**2**	**3**
4(A2)	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	**0**	**1**	**2**	**3**
5(D2)	I found it difficult to work up the initiative to so things ……	**0**	**1**	**2**	**3**
6(S2)	I tended to over-react to situations ……	**0**	**1**	**2**	**3**
7(A3)	I experienced trembling (eg. in the hands) ……	**0**	**1**	**2**	**3**
8(S3)	I felt that I was using a lot of nervous energy ……	**0**	**1**	**2**	**3**
9(A4)	I was worried about situations in which I might panic and make a fool of myself ……	**0**	**1**	**2**	**3**
10(D3)	I felt that I had nothing to look forward to …….	**0**	**1**	**2**	**3**
11(S4)	I found myself getting agitated. ……	**0**	**1**	**2**	**3**
12(S5)	I found it difficult to relax	**0**	**1**	**2**	**3**
13(D4)	I felt sad and depressed ……	**0**	**1**	**2**	**3**
14(S6)	I found it difficult to tolerate interruption to what I was doing …	**0**	**1**	**2**	**3**
15(A5)	I felt I was closed of panic ……..	**0**	**1**	**2**	**3**
16(D5)	I was unable to become enthusiastic about anything	**0**	**1**	**2**	**3**
17(D6)	I felt I wasn't worth much as a person	**0**	**1**	**2**	**3**
18(S7)	I felt that I was rather touchy …….....	**0**	**1**	**2**	**3**
19(A6)	I was aware of the action of my heart in the absence of physical exertion (eg. sense of the heart rate increase, heart missing a beat)	**0**	**1**	**2**	**3**
20(A7)	I felt scared without any good reason ……	**0**	**1**	**2**	**3**
21(D7)	I felt that life was meaningless	**0**	**1**	**2**	**3**

Depression, Anxiety, Stress Scale (DASS-21)

Bahasa Malaysia Version

NAMA : _____ TARIKH : _____

Depression, Anxiety and Stress Scale (DASS-BM)-21

Sila baca setiap kenyataan di bawah dan bulatkan pada nombor 0,1,2 atau 3 bagi menggambarkan keadaan anda sepanjang minggu yang lalu. Tiada jawapan yang betul atau salah. Jangan mengambil masa yang terlalu lama untuk menjawab mana-mana kenyataan.

Skala pemarkahan adalah seperti berikut:

0 **Tidak langsung** menggambarkan keadaan saya
1 **Sedikit atau jarang-jarang** menggambarkan keadaan saya.
2 **Banyak atau kerapkali** menggambarkan keadaan saya.
3 **Sangat banyak atau sangat kerap** menggambarkan keadaan saya

No.	Soalan	**Bulatkan di setiap baris jawapan** **Skala**			
1(S1)	Saya dapati diri saya sukar ditenteramkan ……	**0**	**1**	**2**	**3**
2(A1)	Saya sedar mulut saya terasa kering	**0**	**1**	**2**	**3**
3(D1)	Saya tidak dapat mengalami perasaan positif sama sekali ……	**0**	**1**	**2**	**3**
4(A2)	Saya mengalami kesukaran bernafas (contohnya pernafasan yang laju, tercungap-cungap walaupun tidak melakukan senaman fizikal) ……	**0**	**1**	**2**	**3**
5(D2)	Saya sukar untuk mendapatkan semangat bagi melakukan sesuatu perkara	**0**	**1**	**2**	**3**
6(S2)	Saya cenderung untuk bertindak keterlaluan dalam sesuatu keadaan ….	**0**	**1**	**2**	**3**
7(A3)	Saya rasa menggeletar (contohnya pada tangan) ……	**0**	**1**	**2**	**3**
8(S4)	Saya rasa saya menggunakan banyak tenaga dalam keadaan cemas	**0**	**1**	**2**	**3**
9(A4)	Saya bimbang keadaan di mana saya mungkin menjadi panik dan melakukan perkara yang membodohkan diri sendiri ……	**0**	**1**	**2**	**3**
10(D3)	Saya rasa saya tidak mempunyai apa-apa untuk diharapkan …	**0**	**1**	**2**	**3**
11(S4)	Saya dapati diri saya semakin gelisah ……	**0**	**1**	**2**	**3**
12(S5)	Saya rasa sukar untuk relaks	**0**	**1**	**2**	**3**
13(D4)	Saya rasa sedih dan murung ……	**0**	**1**	**2**	**3**
14(S6)	Saya tidak dapat menahan sabar dengan perkara yang menghalang saya meneruskan apa yang saya lakukan ……	**0**	**1**	**2**	**3**
15(A5)	Saya rasa hampir-hampir menjadi panik/cemas ……	**0**	**1**	**2**	**3**
16(D5)	Saya tidak bersemangat dengan apa jua yang saya lakukan.	**0**	**1**	**2**	**3**
17(D6)	Saya tidak begitu berharga sebagai seorang individu	**0**	**1**	**2**	**3**
18(S7)	Saya rasa yang saya mudah tersentuh ……...	**0**	**1**	**2**	**3**
19(A6)	Saya sedar tindakbalas jantung saya walaupun tidak melakukan aktiviti fizikal (contohnya kadar denyutan jantung bertambah, atau denyutan jantung berkurangan) ……	**0**	**1**	**2**	**3**
20(A7)	Saya berasa takut tanpa sebab yang munasabah ……	**0**	**1**	**2**	**3**
21(D7)	Saya rasa hidup ini tidak bermakna	**0**	**1**	**2**	**3**

APPENDIX G: Medical Outcomes Survey Short Form 36 (SF-36)

English Versions

NAME : _____ **DATE**: _____

Instruction: Answer every question by circling the answer. If you are unsure about how to answer a question, please circle the best answer.

No 1(GH1*). **In general, would you say your health** is:

(circle one number)
Excellent …… **1**
Very Good …….. **2**
Good ……. **3**
Fair …… **4**
Poor …… .**5**

No 2(HT). **Compare to 1 year ago**, how would you rate your health in general now?

	circle one number
Much better now than 1 year ago ……	**1**
Somewhat better now than 1 year ago ……	**2**
About the same ……	**3**
Somewhat worse now than 1 year ago ……...	**4**
Much worse now than 1 year ago …….	**5**

The following items are about activities you might do during a typical day. **Does your health now limit you** in these activities? If so, how much?

CIRCLE ONE NUMBER ON EACH LINE

No.	Activities	Yes, Limited a lot	Yes, limited a little	No, not limited at all
3(PF1)	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports ……..	**1**	**2**	**3**
4(PF2)	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	**1**	**2**	**3**
5 (PF3)	Lifting or carrying groceries ……	**1**	**2**	**3**
6 (PF4)	Climbing **several** flight of stairs ……..……	**1**	**2**	**3**
7(PF5)	Climbing **one** flight of stairs ……	**1**	**2**	**3**
8(PF6)	Bending, kneeling or stooping …….	**1**	**2**	**3**
9(PF7)	Walking **more than a mile** ……..…	**1**	**2**	**3**
10(PF8)	Walking **several block** ……	**1**	**2**	**3**
11(PF9)	Walking **one block** ……	**1**	**2**	**3**
12(PF10)	Bathing or dressing yourself ……	**1**	**2**	**3**

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

CIRCLE ONE NUMBER ON EACH LINE

No.	Problems	Yes	No
13(RP1)	Cut down the **amount of time** you spend on work or other activities ……	**1**	**2**
14(RP2)	**Accomplished less** than you would like ……	**1**	**2**
15(RP3)	Were limited in the **kind** of work or other activities ……	**1**	**2**
16(RP4)	Had **difficulty** performing the work or other activities (for example it look extra effort) ……	**1**	**2**

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problem** (such as feeling depressed or anxious?)

CIRCLE ONE NUMBER ON EACH LINE

No.	Problems	Yes	No
17(RE1)	Cut down the **amount of time** you spend on work or other activities ……	**1**	**2**
18(RE2)	**Accomplished less** than you would like ……	**1**	**2**
19(RE3)	Didn't work or other activities as **carefully** as usual ……	**1**	**2**

No 20(SF1*): During the **past 4 weeks** to what extend has your physical health or emotional problems interfered with your normal social activities with family, friend, neighbors or groups?

	Circle one number
Not at all ……	**1**
Slightly ……	**2**
Moderately ……	**3**
Quite a bit ……	**4**
Extremely ……	**5**

No 21(BP1*): How much **bodily pain** have you had in the **past 4 wee**ks?

	Circle one number
None ……	**1**
Very mild ……	**2**
Mild ……	**3**
Moderate ……	**4**
Severe ……	**5**
Very severe ……	**6**

No 22(BP2*): During the **past 4 weeks**, how much did the pain interfere with your normal work (including both work outside the home **and** housework)?

	Circle one number
Not at all ……	**1**
A little bit ……	**2**
Moderately ……	**3**
Quite a bit ……	**4**
Extremely ……	**5**

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks?**

CIRCLE ONE NUMBER ON EACH LINE

No.	Problems	**All the time**	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
23 (VT1*)	Did you feel full of life? ……	**1**	**2**	**3**	**4**	**5**	**6**
24 (MH1)	Have you been a very nervous person?	**1**	**2**	**3**	**4**	**5**	**6**
25 (MH2)	Have you felt so down in the dumps that nothing can cheer you up? …	**1**	**2**	**3**	**4**	**5**	**6**
26 (MH3*)	Have you felt calm and peaceful? …	**1**	**2**	**3**	**4**	**5**	**6**
27 (VT2*)	Did you have a lot of energy? ……	**1**	**2**	**3**	**4**	**5**	**6**
28 (MH4)	Have you felt downhearted and low ? ……..	**1**	**2**	**3**	**4**	**5**	**6**
29 (VT3)	Did you feel warn out? ……	**1**	**2**	**3**	**4**	**5**	**6**
30 (MH5*)	Have you been a happy person? ..	**1**	**2**	**3**	**4**	**5**	**6**
31 (VT4)	Did you feel tired?	**1**	**2**	**3**	**4**	**5**	**6**

No 32(SF2): During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friend, relative etc)?

	Circle one number
All the time ……	**1**
Most of the time ……	**2**
Some of the time ……	**3**
A little of the time ……	**4**
None of the time ……..	**5**

How **TRUE** or **FLASE** is each of the following statements for you?

CIRCLE ONE NUMBER ON EACH LINE

No.		**Definitely true**	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
33 (GH2)	I seem to get ill more easily than other people ……	**1**	**2**	**3**	**4**	**5**
34 (GH3*)	I am as healthy as anybody I know .	**1**	**2**	**3**	**4**	**5**
35 (GH4)	I expect my health to get worse ….	**1**	**2**	**3**	**4**	**5**
36 (GH5*)	My health is excellent ……	**1**	**2**	**3**	**4**	**5**

Malay Version

NAMA : _____ **TARIKH** : _____

MEDICAL OUTCOMES SURVEY SHORT FORM 36 (SF-36)(BM)

Arahan: Sila bulatkan jawapan bagi setiap soalan pada nombor yang disediakan. Jika tidak pasti tentang jawapan bagi sesuatu soalan, pilihlah jawapan yang paling hamper berdasarkan pendapat anda..

No 1(GH1*). **Secara umum, kesihatan anda boleh dianggap berada di tahap**:

	(Bulatkan satu jawapan)
Cemerlang ……	**1**
Sangat baik ..……..	**2**
Baik ……	**3**
Sederhana ……	**4**
Tidak baik ……..	**5**

No 2(HT). **Berbanding dengan setahun yang lalu**, bagaimana anda menilaikan keadaan kesihatan anda sekarang secara keseluruhan?

	(Bulatkan satu jawapan)
Jauh lebih baik sekarang berbanding dari setahun yang lalu ….	**1**
Lebih baik sekarang berbanding dengan setahun uang lalu ….	**2**
Lebih kurang sama dengan setahun yang lalu ……	**3**
Lebih teruk sekarang berbanding dari setahun yang lalu …….	**4**
Jauh lebih teruk sekarang berbanding dari setahun yang lalu …	**5**

Aktiviti-aktiviti tersenarai di bawah mungkin anda lakukan pada hari biasa. **Adakah kesihatan anda sekarang menghadkan anda** daripada melakukan aktiviti-aktiviti ini? Jika YA, setakat mana?

BULATKAN SATU NOMBOR DISETIAP BARIS JAWAPAN

No.	**AKTIVITI**	**Ya, Sangat Terhad**	**Ya, Terhad sedikit**	**Langsung Tidak Terhad**
3(PF1)	**Aktiviti-aktiviti lasak**, seperti mengangkat barang berat, berlari atau sukan lasak ……	**1**	**2**	**3**
4(PF2)	**Aktiviti-aktiviti sederhana**, seperti mengalih meja, menolak pembersih vakum, boling atau bermain golf …	**1**	**2**	**3**
5 (PF3)	Mengangkat atau membawa barang-barang keperluan dapur ……	**1**	**2**	**3**
6 (PF4)	Menaiki **beberapa** tingkat tangga ……..……	**1**	**2**	**3**
7(PF5)	Menaiki **satu** tingkat tangga ……	**1**	**2**	**3**
8(PF6)	Menunduk, melutut atau membongkok ……	**1**	**2**	**3**
9(PF7)	Berjalan **melebihi jarak sebatu** ……	**1**	**2**	**3**
10(PF8)	Berjalan **setengah batu** ……	**1**	**2**	**3**
11(PF9)	Berjalan **100 ela (sepanjang padang bola/sederet kedai**	**1**	**2**	**3**
12(PF10)	Mandi dan memakai pakaian sendiri ……	**1**	**2**	**3**

Disepanjang **4 minggu yang lepas**, adakah **kesihatan fizikal (jasmani) anda menimbulkan masalah** untuk anda melakukan aktiviti-aktiviti berikut / kerja atau lain lain aktiviti yang anda biasa lakukan?

BULATKAN SATU NOMBOR DISETIAP BARIS JAWAPAN

No.	Problems	Ya	Tidak
13(RP1)	Terpaksa **mengurangkan masa** untuk melakukan sesuatu kerja atau lain lain aktiviti	**1**	**2**
14(RP2)	**Terhad kerja / aktiviti kurang** daripada yang diharapkan **…**	**1**	**2**
15(RP3)	Terhad hanya kepada **jenis kerja tertentu** atau aktiviti lain …	**1**	**2**
16(RP4)	Mengalami **kesukaran** dalam menjalankan kerja atau aktiviti lain (contohnya memerlukan lebih usaha)	**1**	**2**

Sepanjang **4 minggu yang lepas**, adakah **keadaan emosi anda** (seperti berasa sedih dan murung atau gelisah) **mengakibatkan gangguan** terhadap kerja anda atau lain-lain aktiviti biasa anda?

BULATKAN SATU NOMBOR DISETIAP BARIS JAWAPAN

No.	Problems	Ya	Tidak
17(RE1)	Terpaksa **mengurangkan masa** untuk melakukan sesuatu kerja atau lain lain aktiviti ……	**1**	**2**
18(RE2)	**Mencapai tahap kerja / aktiviti kurang** daripada yang diharapkan ……	**1**	**2**
19(RE3)	Tidak dapat melaksanakan kerja atau aktiviti lain dengan **teliti atau cermat** seperti biasa.	**1**	**2**

No 20(SF1*): Sepanjang **4 minggu yang lepas**, sejauh manakah kesihatan fizikal atau masalah emosi mengganggu pergaulan biasa anda dengan keluarga, kawan-kawan, jiran atau kumpulan?

	(Bulatkan satu jawapan)
Langsung tidak ……	**1**
Sedikit ……	**2**
Sederhana ……	**3**
Agak banyak …….	**4**
Terlalu banyak ……	**5**

No 21(BP1*): Sepanjang **4 minggu yang lepas**, sejauh manakah anda mengalami **sakit badan**?

	(Bulatkan satu jawapan)
Tiada ……	**1**
Sangat ringan / sangat sedikit ……	**2**
Ringan / sedikit ……	**3**
Sederhana ……	**4**
Teruk ……	**5**
Sangat teruk ……	**6**

No 22(BP2*): Sepanjang **4 minggu yang lepas**, sejauh manakah kerja harian (termasuk kerja luar **dan** di dalam rumah) anda terganggu disebabkan kesakitan?

	(Bulatkan satu jawapan)
Langsung tidak ……	**1**
Sedikit ……	**2**
Sederhana ……	**3**
Agak banyak ……	**4**
Terlalu banyak ……	**5**

Soalan-soalan berikut adalah berkenaan perasaan dan keadaan anda sepanjang **4 minggu yang lepas**. Berikan satu jawapan yang memberi gambaran yang paling hampir tentang keadaan atau perasaan yang anda alami. **Berapa kerap perasaan tersebut semasa 4 minggu yang lepas?**

BULATKAN SATU NOMBOR DISETIAP BARIS JAWAPAN

No.	Masalah	**Sepanjang masa**	**Hampir sepanjang masa**	**Agak kerap**	**Kadang-kadang**	**Jarang**	**Langsung tidak**
23 (VT1*)	Adakah anda berasa bersemangat / ceria?	**1**	**2**	**3**	**4**	**5**	**6**
24 (MH1)	Adakah anda seorang yang selalu berasa gelisah? …….	**1**	**2**	**3**	**4**	**5**	**6**
25 (MH2)	Adakah anda berasa sangat sedih seolah-olah tiada apa yang boleh menggembirakan anda? …….	**1**	**2**	**3**	**4**	**5**	**6**
26 (MH3*)	Adakah anda merasa aman dan tenteram (tenang)? ……..	**1**	**2**	**3**	**4**	**5**	**6**
27 (VT2*)	Adakah anda berasa bertenaga? ……	**1**	**2**	**3**	**4**	**5**	**6**
28 (MH4)	Adakah anda mengalami perasaan sedih? …….	**1**	**2**	**3**	**4**	**5**	**6**
29 (VT3)	Adakah anda berasa tidak bermaya / bertenaga? ……	**1**	**2**	**3**	**4**	**5**	**6**
30 (MH5*)	Adakah anda dulu seorang yang ceria?	**1**	**2**	**3**	**4**	**5**	**6**
31 (VT4)	Adakah anda verasa letih? ……..	**1**	**2**	**3**	**4**	**5**	**6**

No 32(SF2): Sepanjang **4 minggu yang lalu**, berapa kerapkah **kesihatan fizikal atau masalah emosi** mengganggu pergaulan anda (seperti menziarahi kawan-kawan, sanak saudara dan lain lain)?

	Circle one number
Sepanjang masa ……...	**1**
Hampir sepanjang masa …….	**2**
Kadang-kadang ……	**3**
Jarang ……..…	**4**
Tidak Pernah …….	**5**

Setakat mana setiap pernyataan berikut **BENAR** atau **TIDAK** bagi diri anda??

BULATKAN JAWAPAN DI SETIAP BARIS

No.		**Pasti benar**	**Selalu benar**	**Tidak tahu**	**Selalu tidak**	**Pasti tidak**
33 (GH2)	Saya rasa saya mudah mendapat penyakit berbanding orang lain …	**1**	**2**	**3**	**4**	**5**
34 (GH3*)	Saya sihat seperti mana orang lain yang saya kenali …….	**1**	**2**	**3**	**4**	**5**
35 (GH4)	Saya jangkakan kesihatan saya akan bertambah buruk …….	**1**	**2**	**3**	**4**	**5**
36 (GH5*)	Kesihatan saya sangat baik ……	**1**	**2**	**3**	**4**	**5**

APPENDIX H: Scoring for pre-coded item and its corresponding final values

Domains	Items no.	Pre-coded item value	Final Item Value
i. Physical Function	3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h ,3i	1 2 3	1 2 3
ii. Role-Physical	4a, 4b, 4c, 4d	1 2	1 2
iii. Bodily Pain	7	1 2 3 4 5 6	6 5 4 3 2 1
	8*	Item 7 / Item 8 1 / 1 2 to 6 / 1 1 to 6 / 2 1 to 6 / 3 1 to 6 / 4 1 to 6 / 5	6 5 4 3 2 1
iv. General Health	1, 11b , 11d	1 2 3 4 5	5 4 3 2 1
	11a & 11c	1 2 3 4 5	1 2 3 4 5
v. Vitality	9a & 9e	1 2 3 4 5 6	6 5 4 3 2 1
	9g & 9i	1 2 3 4 5 6	1 2 3 4 5 6
vi. Social Functioning	6	1 2 3 4 5	5 4 3 2 1
	10	1	1

			2 3 4 5	2 3 4 5
vii.	**Role Emotional**	5a, 5b, 5c	1 2	1 2
viii.	**Mental Health**	9b, 9c, 9f	1 2 3 4 5 6	1 2 3 4 5 6
		9d & 9h	1 2 3 4 5 6	6 5 4 3 2 1
ix.	**Reported Health Transition**	2	1 2 3 4 5 6	1 2 3 4 5 6

* Final score for item 8 will depends on the pre-coded response of item 7

APPENDIX I: UMMC Ethic Committee

UNIVERSITI MALAYA
PUSAT PERUBATAN UM

JAWATANKUASA ETIKA PERUBATAN
PUSAT PERUBATAN UNIVERSITI MALAYA
ALAMAT: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
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No. Rujukan: PPUM/MDU/300/04/03

27 Mei 2011

Dr. Mohamad Rodi bin Isa
Jabatan Perubatan Kemasyarakatan & Pencegahan
Pusat Perubatan Universiti Malaya

Tuan,

SURAT PEMAKLUMAN KEPUTUSAN PERMOHONAN MENJALANKAN PROJEK PENYELIDIKAN
The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients: A quasi-experimental study
Protocol No : -
MEC Ref. No : 854.18

Dengan hormatnya saya merujuk kepada perkara di atas.

Bersama-sama ini dilampirkan surat pemakluman keputusan Jawatankuasa Etika Perubatan yang bermesyuarat pada 25 Mei 2011 untuk makluman dan tindakan tuan selanjutnya.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

Norashikin Mahmood
Setiausaha
Jawatankuasa Etika Perubatan
Pusat Perubatan Universiti Malaya

s.k Ketua
Jabatan Perubatan Kemasyarakatan & Pencegahan

UNIVERSITI MALAYA
PUSAT PERUBATAN UM

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE
ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 FAXIMILE: 03-79494638

NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre **ADDRESS:** LEMBAH PANTAI 59100 KUALA LUMPUR	**ETHICS COMMITTEE/IRB REFERENCE NUMBER:** 854.18
PROTOCOL NO: **TITLE:** The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients: A quasi-experimental study	
PRINCIPAL INVESTIGATOR: Dr. Mohamad Rodi bin Isa **TELEPHONE:** **KOMTEL:**	**SPONSOR:**

The following item [✓] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[✓] Borang Permohonan Pindaan Penyelidikan	Ver date: 26 Apr 11
[✓] Protocol Amendment- study design	Ver date:
[ ] Investigator Brochure	Ver date:
[ ] Questionnaire	
[ ] Investigator(s) CV's (if applicable)	

and have been [✓]

[✓] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Investigator are required to:

1) *follow instructions, guidelines and requirements of the Medical Ethics Committee.*
2) *report any protocol deviations/violations to Medical Ethics Committee.*
3) *provide annual and closure report to the Medical Ethics Committee.*
4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
5) *note that Medical Ethics Committee may audit the approved study.*

Date of approval: 25th MAY 2011

c.c Head
Department of Preventive Medicine & Social

Deputy Dean (Research)
Faculty of Medicine

Secretary
Medical Ethics Committee
University Malaya Medical Centre

.....
PROF. KULENTHRAN ARUMUGAM
Deputy Chairman
Medical Ethics Committee

UNIVERSITI MALAYA
PUSAT PERUBATAN UM

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE
ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 FAXIMILE: 03-79494638

MEDICAL ETHICS COMMITTEE COMPOSITION, UNIVERSITY MALAYA MEDICAL CENTRE
Date: 25th MAY 2011

Member (Title and Name)	Occupation (Designation)	Male/Female (M/F)	Tick (✓) if present when above items were reviewed
Chairperson: Prof. Looi Lai Meng	Senior Consultant Department of Pathology	Female	
Deputy Chairperson: Prof. Kulenthran Arumugam	Senior Consultant Medical Education Research and Development Unit (MERDU)	Male	✓
Secretary (non-voting): Cik Norashikin Mahmood	Scientific Officer Medical Development Unit	Female	✓
Members: 1. Y. Bhg. Prof. Dato' Patrick Tan Seow Koon	Deputy Director (Professional)	Male	
2. Prof. Nor Zuraida Zainal	Head Department of Psychological Medicine	Female	✓
3. Dr. Nur Lisa Zaharan	Representative of Head Department of Pharmacology	Female	✓
4. Assoc. Prof. Tan Chong Tin	Representative of Head Department of Medicine	Male	✓
5. Assoc. Prof. Alizan Abdul Khalil	Representative of Head Department of Surgery	Male	✓
6. Tuan Haji Amrahi Buang	Chief Pharmalist Pharmacy Department University Malaya Medical Centre	Male	✓
7. Y. Bhg. Assoc. Prof. Datin Grace Xavier	Representative of Dean Faculty of Law University Malaya	Female	✓
8. Y. Bhg. Datin Aminah bt. Pit Abdul Rahman	Public Representative	Female	
9. Madam Ong Eng Lee	Public Representative	Female	✓

Comments: The MEC of University Malaya Medical Centre is operating according to ICH-GCP guidelines and the Declaration of Helsinki. Member's no. 7, 8 & 9 are representatives from Faculty of Law in the University Malaya and the public, respectively Member no. 10 is by invitation only. They are independent of the hospital or trial site.

.....

PROF. KULENTHRAN ARUMUGAM
Deputy Chairman
Medical Ethics Committee

APPENDIX J: PPUKM Ethic Committee

UNIVERSITI KEBANGSAAN MALAYSIA
The National University of Malaysia

Sekretariat Penyelidikan Perubatan & Industri | Medical Research & Industry Secretariat

UKM 1.5.3.5/244/SPP3
19 July 2011

Associate Professor Dr Zulkifli Md. Zainuddin
Department of Surgery
UKM Medical Centre
Cheras

Dear Dr.,

Approval to conduct research in UKM

Title : *'The Impact of the Applied Progressive Muscle Relaxation Training to the Level of Depression, Anxiety, Stress and Quality of Life among Prostate Cancer Patients – A Quasi-Experimental Study'*

Project Code : **FF-277-2011**

With reference to the above, the Research Committee, Universiti Kebangsaan Malaysia Medical Centre (UKMMC) has approved the following research proposal:

Duration of Study : July 2011 until June 2012
Financial Support : Without Financial Support

Please submit any **Adverse Events Report, Progress Report every 6 months** and **Final Report** upon completion of the research to the Medical Research Secretariat. Please also complete the online registration on ***'National Medical Research Register'*** at www.nmrr.gov.my.

Thank you.

Yours truly,

Professor Dr. Rohaizak Muhammad
Acting Deputy Dean (Research & Industry)
UKM Medical Centre
& Chairman
PPUKM Research Committee
Cheras

Cc.
- *Circulation file*
  FF-277-2011

Sekretariat Penyelidikan Perubatan & Industri, Pusat Perubatan Universiti Kebangsaan Malaysia,
Tingkat 1, Blok Klinikal, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras Kuala Lumpur. Malaysia.
Telefon: +603-9145 5046/5048 Faksimili: +603-91456634. Laman web: http://www.ppukm.ukm.my

UNIVERSITI KEBANGSAAN MALAYSIA
The National University of Malaysia

Jawatankuasa Etika Penyelidikan UKM | ***UKM Research Ethics Committee***

UKM 1.5.3.5/244/SPP/FF-277-2011

19 Julai 2011

Profesor Madya Dr Zulkifli Md. Zainuddin
Jabatan Surgeri
Pusat Perubatan UKM,
Cheras

Saudara,

Kelulusan Etika Menjalankan Penyelidikan di UKM

Dengan segala hormatnya, merujuk kepada perkara di atas.

Sukacita dimaklumkan permohonan untuk kelulusan etika bagi penyelidikan bertajuk **"The Impact of the Applied Progressive Muscle Relaxation Training to the Level of Depression, Anxiety, Stress and Quality of Life among Prostate Cancer Patients -- A Quasi-Experimental Study"** telah diluluskan.

Sekian, terima kasih.

Yang benar,

Profesor Madya (K) Dato' Dr Fuad Ismail
Pengerusi
Jawatankuasa Etika Penyelidikan
Universiti Kebangsaan Malaysia

s.k.

- **Dr Moy Foong Ming**
  Jabatan Sosial & Pencegahan Perubatan
  Fakulti Perubatan, Universiti Malaya
  Lembah Pantai, 59100, Kuala Lumpur

- **Prof Dr Nor Zuraida Zainal**
  Jabatan Perubatan Psikologi
  Fakulti Perubatan, Universiti Malaya
  Lembah Pantai, 59100, Kuala Lumpur

- **Dr Saini Jeffery Freddy Abdullah**
  Jabatan Pemulihan Perubatan
  Fakulti Perubatan, Universiti Malaya
  Lembah Pantai, 59100, Kuala Lumpur

- **Prof Dr Azad Hassan Abdul Razack**
- **Dr Mohamad Rodi Isa (Calon PhD UM)**
  Jabatan Surgeri
  Pusat Perubatan Universiti Malaya
  Lembah Pantai, 59100, Kuala Lumpur

→ Fail FF-277-2011

→ Fail Edaran

FI/Asma'/FF-277-2011/Tanpa Bantuan

Sekretariat Penyelidikan Perubatan & Industri, Pusat Perubatan Universiti Kebangsaan Malaysia,
Tingkat 1, Blok Klinikal, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras Kuala Lumpur. Malaysia.
Telefon: +603-9145 5046/5048 Faksimili: +603-91456634. Laman web: http://www.ppukm.ukm.my

UNIVERSITI KEBANGSAAN MALAYSIA
The National University of Malaysia

Jawatankuasa Etika Penyelidikan UKM | ***UKM Research Ethics Committee***

NAME OF ETHICS COMMITTEE/IRB: Research Ethics Committee, Universiti Kebangsaan Malaysia. **ADDRESS :** Medical Research & Industry Secretariat, Level 1, Clinical Block, UKM Medical Centre, Jalan Yaakob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur. Malaysia.	**ETHICS COMMITTEE/IRB REF NO :** **UKM 1.5.3.5/244/FF-277-2011**
PROTOCOL TITLE : The Impact of the Applied Progressive Muscle Relaxation Training to the Level of Depression, Anxiety, Stress and Quality of Life among Prostate Cancer Patients – A Quasi-Experimental Study	
PRINCIPAL INVESTIGATOR : Associate Professor Dr Zulkifli Md. Zainuddin Department of Surgery UKM Medical Centre Cheras	

The following items (/) have been received and reviewed in connection with the above study to be conducted by the above investigator.

Documents

(/) Research Application Form & Research Proposal
(/) Letter of Approval from Medical Ethics Committee, University Malaya Medical Centre
(/) Information Sheet and Consent Form (English and Malay)
(/) Publication Policy
(/) Questionnaires of the study
- Depression, Anxiety and Stress Scale (DASS-BM)-21 (English and Malay)
- Medical Outcomes Survey Short Form 36 (SF-36) (English and Malay)

(/) GCP Letter of Attending for Dr Mohamad Rodi

The Research Ethics Committee, Universiti Kebangsaan Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any) : _____

Date of Approval: 28 June 2011

Clinical Associate Professor Dato' Dr Fuad Ismail
Chairman
Research Ethics Committee
The National University of Malaysia

Sekretariat Penyelidikan Perubatan & Industri, Pusat Perubatan Universiti Kebangsaan Malaysia,
Tingkat 1, Blok Klinikal, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras Kuala Lumpur. Malaysia.
Telefon: +603-9145 5046/5048 Faksimili: +603-91456634. Laman web: http://www.ppukm.ukm.my

APPENDIX K: UMMC Patient Information Sheet

PATIENT INFORMATION SHEET

Please read the following information carefully, do not hesitate to discuss any questions you may have with your Doctor.

Study Title

The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients

Introduction

It was noted that the anxiety, stress and depression among cancer patients were high. Receiving a diagnosis of prostate cancer can be disturbing experience for many men. Other than the possibility of death, they are also faced with serious challenges to their self-esteem particularly in terms of their masculinity. Cancer prostate patients will experience elevated levels of anxiety, stress and depression with some data said that these were due to loss of previously social and personal activities and abilities. There is lots of evidence that relaxation therapy may improve psychological outcomes in many diseases like after coronary artery bypass graft surgery, bronchial asthma, after hysterectomy etc. It also can reduce the pain levels in the osteoarthritis patients.

What is the purpose of this study?

The study aims is to determine the effectiveness of the progressive deep muscle relaxation (PMR) as an adjunct treatment to reduce the levels of anxiety, stress and depression among prostate cancer level in UMMC.

What are the procedures to be followed?

The patients will be selected by using inclusion criteria and then they will be divided into 2 groups by using the block randomization method. Respondents will be asked to answer the DASS and Health Related Quality of life (HRQoL) Questionnaires. The experimental group will be given progressive deep muscle relaxation therapy but for the control no intervention given. Some series of therapy will be given and the CD of the therapy will also be given in order to the patients do it at home. Follow up will be done to the patient after 3 and 6 months to assess again the level of anxiety, stress and depression and also the level of the quality of life. The data from the questionnaire will be tabulated and analyzed with other respondents information

Who should not enter the study?

All the prostate cancer patients in UMMC who have been selected by the researcher after considered the inclusion and exclusion criteria.

What will be benefits of the study:

(a) to you as the subject?

The respondents will be getting the benefits by applying the therapy to reduce their psychological problem and increase their quality of life. It is just a therapy which is no side effect if compared to medication. They can do it at home at any time when they are free.

(b) to the investigator?

The data available will be beneficial to the patients at large and can contribute to the effectiveness of the progressive deep muscle relaxation as an adjunct treatment to reduce the level of anxiety, stress and depression to the prostate cancer patients. It also can improve the quality of life if the intervention given significantly effective.

What are the possible drawbacks?

There are no risks to you except reveal some sensitive information related to your perception about your anxiety, stress and depression and also your current quality of life

Can I refuse to take part in the study?

Your participation in this study is voluntary. Your decision to participate or otherwise will not affect your current or future relationship with the medical centre in anyway. In addition if after you join the study and later you decide to withdraw, you are free to do so at any time

Who should I contact if I have additional questions during the course of the study?

If you have any question or need clarification about this study feel free to contact any of the following.

i. Dr. Mohamad Rodi bin Isa at 019-3453515, email: demangsura@yahoo.co.uk
ii. Dr. Moy Foong Ming at 03-79676657, email: moyfm@um.edu.my

APPENDIX L: UKMMC Patients Information sheet

INFORMATION SHEET FOR PATIENT

1.0 Research Title

The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients: A Quasi-Experimental Study

2.0 Introduction

It was noted that the anxiety, stress and depression among cancer patients were high. Receiving a diagnosis of prostate cancer can be disturbing experience for many men. Other than the possibility of death, they are also faced with serious challenges to their self-esteem particularly in terms of their masculinity. Cancer prostate patients will experience elevated levels of anxiety, stress and depression with some data said that these were due to loss of previously social and personal activities and abilities. There is lots of evidence that relaxation therapy may improve psychological outcomes in many diseases like after coronary artery bypass graft surgery, bronchial asthma, after hysterectomy etc. It also can reduce the pain levels in the osteoarthritis patients.

3.0 What would this involve?

The study aims is to determine the impact of the applied progressive muscle relaxation training (PMRT) to the levels of depression, anxiety, stress and quality of life among prostate cancer patients.

The patients will be selected by using inclusion and exclusion criteria. Selected patients at University Malaya Medical Centre are chosen as group of intervention and patients at University Kebangsaan Malaysia Medical Centre as a control group. Respondents will be asked to answer the DASS and Health Related Quality of life (HRQoL) Questionnaires. The experimental group will be given applied progressive muscle relaxation training therapy but for the control no intervention given. Some series of therapy will be given and the CD of the therapy will also be given in order to the patients do it at home. Follow up will be done to the patient after 4 and 6 months to assess again the level of anxiety, stress and depression and also the level of the quality of life. The data from the questionnaire will be tabulated and analyzed with other respondents information

4.0 The benefits

4.1 to you as the subject?

The respondents will be getting the benefits by applying the therapy to reduce their psychological problem and increase their quality of life. It is just a therapy which is no side effect if compared to medication. They can do it at home at any time when they are free.

4.2 to the investigator?

The data available will be beneficial to the patients at large and can contribute to the impact of applied progressive muscle relaxation training to the level of anxiety, stress and depression to the prostate cancer patients. It also can improve the quality of life if the intervention given significantly effective.

5.0 The risks

There are no risks to you except reveal some sensitive information related to your perception about your anxiety, stress and depression and also your current quality of life

6.0 Confidentiality

The result of the data obtained will be reported in a collected manner with no reference to a specific
individual. Hence, the data from each individual will remain confidential.

7.0 Do I have to take part?

The participation into this study is voluntary. If you prefer not to take part, you do not have to give reason and your decision will not affect the treatment given. Your decision to participate or otherwise will not affect your current or future relationship with the medical centre in anyway.

8.0 The right to withdraw

Patient has the right to withdraw from the study at any time without affecting the future treatment. In addition if after you join the study and later you decide to withdraw, you are free to do so at any time

9.0 Payment and compensation

You do not have to pay for participating in this study. Similarly, no payment is available to you for
participating in this study.

If I have any questions, whom can I ask at any time point of the study?

Prof. Dr. Zulkifli bin Zainuddin
Department of Surgery, UKMMC
Phone Number : 03-9145 6227
Mobile : 012-2006434

MAKLUMAT UNTUK PESAKIT

1.0 Tajuk Penyelidikan

Kesan "*Applied Progressive Muscle Relaxation Training*" ke atas paras kemurungan, kerisauan, tekanan dan kualiti hidup di kalangan pesakit kanser prostat : Kajian "Quasi-Experimen"

2.0 Pengenalan

Telah diketahui bahawa paras kemurungan, kerisauan dan tekanan dikalangan pesakit kanser adalah tinggi. Apabila pesakit diberitahu mengidap prostat kanser akan mengganggu psikologi di kalangan lelaki. Kebarangkalian lain seperti kematian, mereka juga berhadapan dengan cabaran terhadap diri sendiri seperti mencabar sifat kelakian mereka. Pesakit prostate kanser juga mengalami peningkatan paras kemurungan, kerisauan, dan tekanan dan beberapa data telah mendapati pesakit telah kehilangan keupayaan dan aktiviti pesakit it usendiri. Beberapa kajian "relaksasi" telah mendapati boleh membantu dalam memulihkan beberapa penyakit psikologi dikalangan pesakit seperti pembedahan pintasan arteri koronari, asma, selepas pembedahan histerektomi dan sebagainya. Ia juga di dapati boleh mengurangkan tahap kesakitan di kalangan pesakit sendi.

3.0 Apa yang akan dilakukan?

Tujuan kajian ini adalah untuk mengetahui Kesan "Applied Progressive Muscle Relaxation" ke atas paras kemurungan, kerisauan, tekanan dan kualiti hidup di kalangan pesakit kanser prostat. Pesakit akan dipilih mengikut criteria inklusi dan eksklusi. Pesakit yang telah dipilih di Pusat Perubatan Universiti Malaya akan menjalani intervensi terapi relaksasi dan pesakit di Hospital Selayang dipilih sebagai control. Semua pesakit akan perlu menjawab soalan daripada Skala Kemurungan, Kerisauan, dan Tekanan (DASS) dan soalan Kualiti Hidup (SF-36). Kumpulan eksperimen akan diberi terapi "Applied Progressive Muscle Relaxation" dan kumpulan control tidak diberi apa apa intervensi. Beberapa siri terapi akan diberikan kepada pesakit. Penilain susulan akan di buat selepas 4 dan 6 bulan to menilai tahap Kemurungan, Kerisauan, dan Tekanan dan Kualiti Hidup. Data yang terkumpul akan dianalisis untuk mendapat kesimpulan kajian.

4.0 Faedah penyelidikan

4.1 Kepada pesakit ?

Pesakit akan mendapat faedah dengan menjalani terapi relaksasi untuk mengurangkan masalah psikologi dan meninggikan kualiti hidup. Ini adalah terapi yang tidak mempunya kesan sampingan berbanding pengunaan ubat-ubatan. Ia boleh dilakukan di rumah dan di mana sahaja mereka berada.

4.2 Kepada penyelidik ?

Data yang didapati akan member faedah yang besar kepada pesakit untuk mengetahu kesan "Applied Progressive Muscle Relaxation" ke atas paras kemurungan, kerisauan dan tekanan. Terapi itu juga boleh meningkatkan kualiti hidup jika keberkesanannya signifikans.

5.0 Risiko

Tiada risiko terhadap kajian kecuali beberapa keterangan sensitive yang berkaitan dengan kemurungan, kerisauan dan tekanan dan kualiti hidup pesakit yang terkini.

6.0 Kerahsiaan

Keputusan yang diperolehi akan dimaklumkan secara keseluruhan (kolektif) dan tidak akan merujuk pada nama individu pesakit. Maka maklumat dan keputusan dari setiap pesakit adalah sulit

7.0 Perlukah saya mengambil bahagian?

Penglibatan dalam penyelidikan ini adalah secara sukarela. Sekiranya anda tidak bersetuju, anda tidak perlu memberikan sebab dan ini tidak menjejaskan rawatan yang akan diberikan

8.0 Hak untuk menarik diri

Pesakit boleh menarik diri dari penyelidikan ini pada bila-bila masa tanpa menjejaskan rawatan yang akan diberikan

9.0 Bayaran dan pampasan

Anda tidak akan dikenakan apa-apa bayaran dan anda juga tidak akan dibayar bagi penglibatan dalam
penyelidikan ini

Jika saya ada sebarang pertanyaan, siapa boleh saya hubungi?

Prof. Dr. Zulkifli bin Zainuddin
Jabatan Pembedahan, PPUKM
Tel : 03-9145 6227
Mobile : 012-2006434

APPENDIX M: UMMC Consent by Patient for Clinical Research

I, ……..… Identity Card No…….……
(Name of Patient) of
……
(Address)

hereby agree to take part in the clinical research (clinical study/questionnaire study/drug trial) specified below:

Title of Study: The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients
……
MOHAMAD RODI BIN ISA
the nature and purpose of which has been explained to me by Dr. ..……
(Name & Designation of Doctor)

……..…… and interpreted by ……..……
(Name & Designation of Interpreter)

…….. to the best of his/her ability in …….……
language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date: ……...…….. Signature or Thumbprint ……..……
(Patient)

IN THE PRESENCE OF

Name ……..…..……...…)
)
Identity Card No. ……..……..……) Signature ……
) (*Witness for Signature of Patient)*
Designation ……..……)

I confirm that I have explained to the patient the nature and purpose of the above–mentioned clinical research.

Date ……. Signature ……
(Attending Doctor)

CONSENT BY PATIENT
FOR
CLINICAL RESEARCH

FPU-DOF-BK-012-05-R01

R.N.
Name
Sex
Age
Unit

KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL

Saya,……..……. **No. Kad Pengenalan** ……..
(Nama Pesakit)

beralamat…….……..……
(Alamat)

dengan ini bersetuju menyertai dalam penyelidikan klinikal (pengajian klinikal/pengajian soal–selidik/percubaan ubat–ubatan) disebut berikut:

Tajuk Penyelidikan: The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients
……..……

MOHAMAD RODI BIN ISA
yang mana sifat dan tujuannya telah diterangkan kepada saya oleh Dr. ……
(Nama & Jawatan Doktor)

……..…… **mengikut terjemahan** ……..……
(Nama & Jawatan Penterjemah)

……. **yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Bahasa / loghat**……

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan methodologi, risiko dan komplikasi (mengikut kertas maklumat pesakit). Selepas mengetahui dan memahami semua kemungkinan kebaikan dan keburukan penyelidikan klinikal ini, saya merelakan/mengizinkan sendiri menyertai penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik diri dari penyelidikan klinikal ini pada bila–bila masa tanpa memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan dari doktor yang merawat.

Tarikh: …….. **Tandatangan/Cap Jari** ……
(Pesakit)

DI HADAPAN

Nama ……)

No. K/P……..) **Tandatangan** ……
(Saksi untuk Tandatangan Pesakit)
Jawatan ……..……..)

Saya sahkan bahawa saya telah menerangkan kepada pesakit sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh: ……..……. **Tandatangan** ……
(Doktor yang merawat)

KEIZINAN OLEH PESAKIT
UNTUK
PENYELIDIKAN KLINIKAL

No. Pend.
Nama
Jantina
Umur
Unit

CONSENT BY RESPONSIBLE RELATIVE FOR CLINICAL RESEARCH

I, ……. Identity Card No……...……
(Name)
of ……
(Address)

hereby agree that my relative …….. I.C. No……..……
(Name)
participate in the clinical research (clinical study/questionnaire study/drug trial) specified below:–

Title of Study: The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients
……
MOHAMAD RODI BIN ISA
the nature and purpose of which has been explained to me by Dr. ..……..……
(Name & Designation of Doctor)

……..… and interpreted by ……..……
(Name & Designation of Interpreter)

…… to the best of his/her ability in ……..…….……
language/dialect.

I have been informed of the nature of this clinical research in terms of procedure, possible adverse effects and complications (as per patient information sheet). I understand the possible advantages and disadvantages of participating in this research. I voluntarily give my consent for my relative to participate in this research specified above.

I understand that I can withdraw my relative from this clinical research at any time without assigning any reason whatsoever and in such situation, my relative shall not be denied the benefits of usual treatment by the attending doctors. Should my relative regains his/her ability to consent, he/she will have the right to remain in this research or may choose to withdraw.

Date: …….. Relationship to Patient …… Signature or Thumbprint ……

IN THE PRESENCE OF

Name ……..…..)

Identity Card No. …….) Signature ……
(Witness)

Designation ……)

I confirm that I have explained to the patient's relative the nature and purpose of the above–mentioned clinical research.

Date ……. Signature ……
(Attending Doctor)

CONSENT BY
RESPONSIBLE RELATIVE FOR
CLINICAL RESEARCH

R.N.
Name
Sex
Age
Unit

KEIZINAN OLEH WARIS YANG BERTANGGUNGJAWAB UNTUK PENYELIDIKAN KLINIKAL

Saya,……..…….…. **Kad Pengenalan** ……..…..…
(Nama Waris yang bertanggungjawab)

beralamat……..……
(Alamat)
dengan ini bersetuju supaya saudara saya……..……
menyertai
(Nama Pesakit)

dalam penyelidikan klinikal (pengajian klinikal/pengajian soal-selidik/percubaan ubat-ubatan) disebut berikut:

Tajuk Penyelidikan: The impact of the progressive deep muscle relaxation to the level of depression, anxiety, stress and quality of life among prostate cancer patients: Randomized controlled trial
……..……
MOHAMAD RODI BIN ISA
yang mana sifat dan tujuannya telah diterangkan kepada saya oleh Dr.……
(Nama & Jawatan Doktor)

…… **mengikut terjemahan** ……..……
(Nama & Jawatan Penterjemah)
…… **yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Bahasa / loghat** ……

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan metodologi, risiko dan komplikasi (mengikut kertas maklumat pesakit). Saya mengetahui dan memahami semua kemungkinan kebaikan dan keburukan penyelidikan klinikal ini. Saya merelakan/mengizinkan saudara saya menyertai penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik balik penyertaan saudara saya dalam penyelidikan klinikal ini pada bila–bila masa tanpa memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan dari doktor yang merawat. Sekiranya saudara saya kembali berupaya untuk memberi keizinan, beliau mempunyai hak untuk terus menyertai kajian ini atau memilih untuk menarik diri.

Tarikh: ……..… **Pertalian dengan Pesakit** …..…… **Tandatangan/Cap Jari Waris yang bertanggungjawab**
……

DI HADAPAN
Nama ……..…..)
)
No. K/P……) **Tandatangan** ……
) *(Saksi untuk Tandatangan*
Jawatan……..……) *Waris yang Bertanggungjawab)*

Saya sahkan bahawa saya telah menerangkan kepada waris yang bertanggungjawab sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh: ……..…… **Tandatangan** ……
(Doktor yang merawat)

KEIZINAN OLEH PESAKIT
UNTUK
PENYELIDIKAN KLINIKAL

No. Pend.
Nama
Jantina
Umur
Unit

APPENDIX N: UKMMC Consent form for Patient

CONSENT FORM FOR PATIENT

Research Title

The impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients: A Quasi-Experimental Study

I have read the information of this study and have also been given the explanation by a doctor about the

purpose of this document. I understand the aims of the study including its risks and benefits. I

_____(name), IC no: _____, ***agree/disagree** to participate in the study as stated above.

I ***would like to know/don't want to know** the result of this study (* delete where necessary)

Signature : _____ Date : _____

Witness		**Medical Officer**	
Name	:	**Name**	:
IC no	:	**IC no**	:
Signature	:	**Signature**	:
Date	: _____	**Date**	: _____

BORANG KEIZINAN DARIPADA PESAKIT
Tajuk Penyelidikan

Kesan "Applied Progressive Muscle Relaxation" ke atas paras kemurungan, kerisauan, tekanan dan kualiti hidup di kalangan pesakit kanser prostat : Kajian "Quasi-Experimen"

Saya telah membaca maklumat tentang kajian ini dan juga telah diberi penerangan oleh doktor tentang
dokumen ini. Saya faham akan tujuan kajian ini termasuk berkaitan risiko dan manfaatnya. Saya
_____ (nama) no. KP _____, ***bersetuju/tidak bersetuju** untuk mengambil bahagian dalam kajian yang telah dinyatakan di atas ini.

Saya ***ingin mengetahui/tidak ingin mengetahui** keputusan penyelidikan ini (*potong mana yang tidak berkenaan)

Tandatangan : _____ Tarikh : _____

Saksi		**Pegawai Perubatan**	
Nama	:	**Nama**	:
No KP	:	**No KP**	:
Tandatangan	:	**Tandatangan**	:
Tarikh	: _____	**Tarikh**	: _____

APPENDIX O: Registration of the Trial

www.irct.ir

trial has now been registered in IRCT and allocated a unique code Your clinical

Registration ID in IRCT	IRCT201103176085N1
Name	Mohamad Rodi Isa
Email	mdrodi@siswa.um.edu.my
Project number	1
Membership Number	6085

Your trial is now registered with Iranian Registry of Clinical Trials. Please make every effort to keep your trial information up to date.

You can update your trial in user's main page by logging in using your username (your e-mail address) and password. Please don't hesitate to contact IRCT administration if you need help.

Best Regards

Iranian Registry of Clinical Trials, NO.211, Opposite Avesta park, Azadi St., Tehran, 14199-43471 Iran Tel: 00982166582501 Fax: 00982166582535 Email: irct@hbi.ir

mail please change "encoding" in -not read Persian part of this e Please note: If you can "(8-your browser to "Unicode (UTF

سلام
خوشبختم كه به اطلاع برسانم كه كارآزمايي شما در مركز ثبت كارآزمايي ايران به ثبت رسيد .از شما تقاضا مي شود تا تمامي تلاش خود را براي بروز نگه داشتن اطلاعات مربوط به كارآزمايي ثبت شده خود بنماييد.

شما مي توانيد از محل صفحه اصلي كاربر اقدام به بروز رساني كارآزمايي ثبت شده خود نماييد. براي اين منظور لازم است ابتدا با استفاده از شناسه كاربري (آدرس پست الكترونيكي خود) و رمز عبور خود وارد سايت مركز ثبت كارآزمايي ها شويد. در صورت نياز به كمك لطفا با تيم اجرايي مركز ثبت كارآزمايي هاي باليني ايران تماس بگيريد.

با تشكر

معاونت تحقيقات وفن آوري
تيم اجرايي مركز ثبت كارآزمايي هاي باليني ايران
تهران، خيابان آزادي
روبروي پارك اوستا، شماره 211
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